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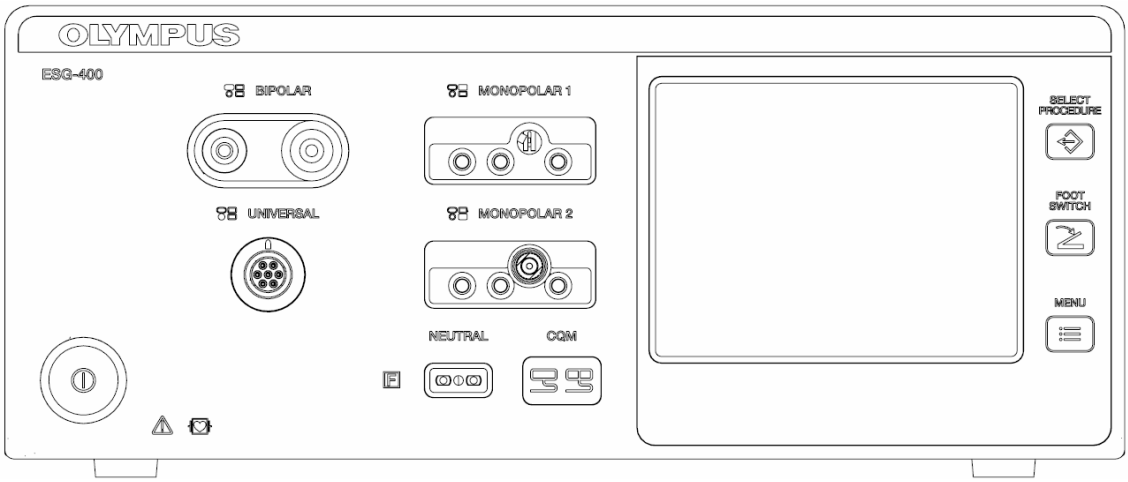

MAINTENANCE / ON-SITE - MANUAL

Electro Surgical Generator

ESG-400

7.022.211 / ISSUE 4

INTRODUCTION

Introduction

The intended use depends on the approval of the country. Refer to the instructions for use of the electrosurgical unit.

Maintenance instructions

This maintenance manual contains essential information on using and maintaining this electrosurgical generator safely and effectively. Instructions for the operation of this electrosurgical generator and related danger, warnings and cautions concerning electrosurgery are beyond the scope of this maintenance manual. Before using and maintaining, thoroughly review this manual and the instructions for use or maintenance manuals of all equipment which will be used during maintenance. Use the equipment as instructed. Keep this manual in a safe, accessible location. If you have any questions or comments about any information in this maintenance manual, contact Olympus.

Signal words

The following signal words are used throughout this maintenance manual:

DANGER	Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.
NOTE	Indicates additional helpful information.

User qualifications

The user must have received appropriate training in using this electrosurgical generator. The following instructions are for use by qualified personnel only. Use of this maintenance manual by other individuals is prohibited. The training will be provided by authorized representatives of Olympus during installation and commissioning.

NOTE	The user must have received appropriate training in using, servicing, adjustment, updating and upgrading this electrosurgical generator.

Federal Law of the USA restricts this device to use by, or on the order of, a physician.

High frequency leakage current or spark discharge may cause user burns.

Follow the dangers, warnings and cautions given below when handling and servicing this electrosurgical unit. This information is to be supplemented by the dangers, warnings and cautions given in each chapter.

User-related error prevention

WARNING **Improper use**

The safety and effectiveness of electrosurgical interventions depend not only on the design of the equipment used, but also to a major extent on factors which are under the control of the user. It is therefore extremely important to read, understand and follow the instructions supplied with the electrosurgical generator and the accessories in order to ensure safety and effectiveness.

Always use the electrosurgical generator as outlined in this maintenance manual. Improper use will not only impede functions and prevent optimum performance, but may cause equipment damage and / or complications. Before each use, always inspect the equipment as outlined in this maintenance manual.

WARNING **Annual safety checks / Inspection**

The electrosurgical generator and the footswitch must undergo a safety check in yearly intervals in accordance with the national statutory regulations (refer to chapter 7 “Inspection”).

Environmental conditions

CAUTION **Interference of the unit with other equipment**

Be sure that this electrosurgical unit is not used adjacent to or stacked with other equipment (other than the components of this electrosurgical unit or system) to avoid electromagnetic interference.

Before use, thoroughly confirm the compatibility of all equipment.

To ensure electrical safety, the electrosurgical unit should not be used in conjunction with:

- Electrical equipment whose safety against leakage current is not guaranteed.
- Electrosurgical equipment whose safety in combined use is not guaranteed.

The electrosurgical generator complies with the electromagnetic compatibility (EMC) standard. Nevertheless, when the electrosurgical generator is active it may disturb neighboring electronic equipment. If an auxiliary computer system is in use together with the electrosurgical generator and endoscopic imaging techniques, the image on the monitor might freeze or blackout. Follow the instructions in “Electromagnetic Compatibility (EMC) information” in the Appendix of the instruction for use regarding electromagnetic ambient conditions.

Never loop the cords (active cord, bipolar cord, neutral electrode cord) or bundle cords together with cords belonging to other medical equipment. The high frequency signals or spark discharge noise generated by the unit may interfere with the operation of other medical equipment.

Do not use the electrosurgical unit in a location exposed to strong electromagnetic radiation (microwave or short-wave medical treatment equipment, Magnetic Resonance Imaging, radio or mobile phone equipment). Electrosurgical unit malfunction can occur.

CAUTION **Unsuitable temperature and humidity**

The electrosurgical generator should only be used under the conditions as described in chapter 1-3 (Limitations). Use under other conditions may impede normal performance and / or result in equipment damage.

Accessories

WARNING **Mechanical stress**

Do not apply excessive bending, straining, or squeezing force to any cords. It may cause malfunction.

CAUTION **Non-compatible accessories and accessory damage**

The electrosurgical generator shall only be used with compatible accessories. When connecting accessories (cords, electrodes, HF instruments) avoid output settings where the maximum output voltage of the electrosurgical generator may exceed the rated accessory voltage (refer to “Mode characteristics”, “Output characteristics” in the Appendix of the instruction for use, and the instruction manual of the accessory). For a list of compatible neutral electrodes, refer to “Specifications” in the Appendix of the instruction for use.

Before use, the electrosurgical unit and accessories must be examined for damage. All communication cables and its plugs must be free of scratches and cracks. Cables and accessories with damaged insulation or connections must not be used.

Electric shock

WARNING **Grounding failure**

To prevent the risk of electric shock, the housing of the electrosurgical unit must be grounded. Always connect the power cord plug to a properly grounded wall outlet. Do not use a 3-pin / 2-pin adapter, as it can impair safe operation of the unit.

WARNING **User shock**

To prevent user shock, malfunction and damage of the electrosurgical unit, keep liquids away from all electrical equipment.

When taking measurements or troubleshooting of the electrosurgical unit, take appropriate precautions, such as using isolated tools and equipment, using the “one hand rule,” etc.

CAUTION **Injury during servicing**

When the housing is opened, there is a danger of electric shock. The unit must only be serviced by authorized technicians.

Burns

WARNING **User**

The maximum output voltage characteristics of the electrosurgical generator are shown in the diagrams in “Output characteristics” in the Appendix of the instruction for use. When setting the power level, first set it to a low level and increase it gradually. If the output is initially set to a high level, the electrode’s insulation may be damaged and cause user and / or patient burns. However, certain modes may present an unacceptable risk at low output power settings. For example, with the PulseCut fast mode or PulseCut slow mode, the risk of an excessive thermal effect rises if the output power setting is too low. Therefore, it is recommended that you perform basic testing before using the electrosurgical generator. If the instruction manual of the HF instrument to be used stipulate a rated voltage, the output should be set so that it does not exceed that voltage.

High frequency, high voltage signals that can cause severe burns are present in the monopolar / bipolar sockets described in this maintenance manual. Take appropriate precautions when testing and troubleshooting this area of the electrosurgical unit.

Fire / Explosion

DANGER **Ignitable anaesthetics / fire supporting gases**

The risk of flammable gases or other materials being ignited exists with any contact of electrical energy. Precautionary measures must be taken to keep flammable materials and substances away from an active electrosurgical unit (do not use flammable anesthetics, nitrous oxide or oxygen). Otherwise, explosion or fire may result and cause serious injuries. This electrosurgical unit is not explosion-proof. Do not use the unit within an explosion zone.

WARNING **Ignitable cleaning- and disinfection agents**

Flammable agents used for cleaning and disinfection must be allowed to evaporate before the electrosurgical unit is used and serviced.

Non-flammable agents should be used for cleaning and disinfection wherever possible.

WARNING **Risk of fire**

Disconnect the power plug before changing the fuses! Replace fuses as marked. The fuses must only be replaced by authorized technicians.

Hazards and complications

WARNING **Contamination**

The electrosurgical unit may be contaminated with infections materials; therefore, all surfaces of the unit's housing should be cleaned before servicing according to chapter 1-8 (Cleaning).

WARNING **Output performance**

Should any abnormal output be suspected during operation, immediately terminate the use of the equipment by releasing the footswitch. If the footswitch does not react, switch off the electrosurgical unit. Otherwise, malfunction of the equipment may cause an unintended increase in output.

WARNING **Service persons**

Take additional precautions for service technicians, when using the unit's service operation mode (see chapter 15, Service operation mode).

CAUTION **Unit defect**

To prevent electrosurgical unit damage, never short-circuit electrodes (accessories, neutral electrodes).

In the event of a defect or malfunction in the unit, an undesirably high output power may be emitted.

DANGER **Unit defect**

Never use the electrosurgical unit if an abnormality is suspected.

Repair and Maintenance

CAUTION **Repair**

Repairs must only be carried out by Olympus or a firm authorized by Olympus.

CAUTION **Maintenance**

Preventive maintenance (inspection / periodic safety check) must only be carried out by a qualified person / technician.

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CHAPTER 1: PRODUCT SPECIFICATIONS

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1 Outline

1-1 Intended Use

The intended use depends on the approval of the country. Refer to the instructions for use of the electrosurgical generator.

1-2 Compatibility

This product can be used in combination with the products listed in compatibility table.

1-3 Expected service life

The expected service life is 10 years.

2 Features

The ESG-400 is a reusable, non-sterile electrosurgical generator with different mono- and bipolar cutting and coagulation modes. The maximum output power is 320 W.

On the front side it features a touch screen display that displays the connection status of accessories and peripherals connected to the electrosurgical generator. It is also used to show and modify the output settings (e.g. mode, output power, effect) as well as to control other functions (e.g. save settings).

In addition the ESG-400 has a bipolar socket, two monopolar sockets, a neutral electrode socket, and a universal socket to connect applicators with instrument recognition. The power switch turns the generator on and off.

Two contact quality indicators (one for split and one for non-split electrodes) are green illuminated if neutral electrodes are correctly connected. Three additional push buttons allow recalling a previously saved setting (Select Procedure), to assign the footswitches to specific output sockets (Footswitch), and to control several other functions (Menu), e.g. select language, touch tone control, output volume, or brightness.

On the rear panel the volume control, a ventilation hole, the equipotential bonding point, the AC power socket, and two footswitch sockets can be found. Furthermore, for the connection of peripheral equipment 26-pin plugs respectively 14-pin plugs can be connected to the LINK-IN or to the LINK-OUT socket.

On the bottom panel, a docking socket is featured. It can be used to connect the ESG-400 directly to the USG-400 and upcoming devices. The ESG-400 is compatible with the new USG-400 ultrasonic generator to enable the use of combined (US + HF) instruments.

2-1 Application Modes

Monopolar Cut:

- PureCut (Cutting of varying tissue structures; 3 Effects)
- BlendCut (Cutting of varying tissue structures; 3 Effects)
- PulseCut slow (Intermittent cutting; 3 Effects)
- PulseCut fast (Intermittent cutting; 3 Effects)

Monopolar Coagulation:

- SoftCoag (Coagulation of tissue with little sticking and carbonization; 3 Effects)
- ForcedCoag (Fast and effective coagulation; 3 Effects)
- SprayCoag (Contact-free surface coagulation with little penetration depth; 3 Effects)
- PowerCoag (Fast and effective coagulation with increased dissection capabilities; 3 Effects)

Bipolar Cut:

- BipolarCut (All bipolar cutting procedures of tissue structures; 3 Effects)
- SalineCut (Cutting in conductive fluid; 3 Effects; only available via UNIVERSAL socket)

Bipolar Coagulation:

- BiSoftCoag (Coagulation with little sticking and carbonization; 3 Effects)
- AutoCoag (Coagulation with little sticking and carbonization; 3 Effects)
- SalineCoag (Coagulation in conductive fluid; 3 Effects; only available via UNIVERSAL socket)

- HardCoag (Controlled tissue coagulation; 3 Effects)
- RFCoag (Controlled deep tissue coagulation; with and without RCAP) FineCoag (Coagulation of tissue with little sticking and carbonization; 1 Effect)

The modes have preset power levels that may be customized by the user in a defined range.

2-2 Accessories

Footswitch Double Pedal (WB50402W): It has a blue pedal that is used to activate the selected coagulation mode and a yellow pedal that is used to activate the selected cutting mode.

Footswitch Single Pedal (optional; WB50403W): It has a blue pedal that is used to activate the selected coagulation mode

P-Cord (optional; MAJ-814): The P-cord is used to connect a patient plate to the ESG-400.

3 Limitations

(1) Use this product under the supervision of a doctor at a medical facility.
(2) Do not use this product in combination with the products other than those designated by Olympus.
(3) This product shoul be used, transported or stored in the following environment.

Operation environment	**Temperature**	+ 10…+ 40°C
	Relative humidity	30…85%, non-condensing
	Atmospheric pressure	70…106 kPa
Transportation and storage environment	**Temperature**	- 25…+ 60°C
	Relative humidity	10…85%, non-condensing
	Atmospheric pressure	50…106 kPa

4 Specifications

4-1 ELECTROSURGICAL GENERATOR ESG-400 (REF: WB91051W)

Power supply	**Voltage range**	100…120 V~ / 220…240 V~
	Frequency	50 / 60 Hz
	Maximum input power	1500 VA
	Power fuse	10 A (only FST-series from Schurter)
	Power connection line	IEC 60320-1 / C13 Maximum length: 4.5 m
	Terminal for potential equalization	Yes
Size, weight and packaging	**Width x Depth x Height**	370 × 465 × 156 mm
	Volume	25752 cm³
	Weight of generator	12.5 kg
	Weight of packaging	2.3 kg
	Type of packaging	Cardboard and expanded polypropylene material
Classification	**Protection class according to IEC 60601-1**	CF, Class I
	Classification according to MDD 93/42/EEC	IIb
Output	**High frequency functions**	Monopolar / Bipolar
	High frequency	430 kHz ±20%
	Maximum high frequency power	320 W
	All modes	25% duty cycle (e.g. 10 s activated / 30 s deactivated)
	RFCoag (with or without RCAP)	100% duty cycle

Sockets	**MONOPOLAR 1**	3-pin (∅ 4 mm), Valleylab standard; coaxial (∅ 8 mm), Bovie standard
	MONOPOLAR 2	3-pin (∅ 4 mm), Valleylab standard; coaxial (∅ 5 / 9 mm), Erbe standard
	BIPOLAR	2-pin (∅ 4 mm, pin spacing 28.8 mm), Valleylab standard; coaxial ($\varnothing_{inner}$ 8 mm, $\varnothing_{outer}$ 4 mm), Erbe standard
	UNIVERSAL	7-pin, Olympus standard
	Neutral electrode	Single or split, 10 mm plug
Contact quality monitor (CQM)	**Allowable resistance range for split type neutral electrodes**	10...155 Ω ±15 Ω
	Allowable resistance range for non-split type neutral electrodes	< 10 Ω ±5 Ω

4-2 Power cords (4.5 m angled plug)

Power cords	**WA95621A**	Many European countries Type E/F
	WA95622A	USA, Canada and other countries Type B
	WA95623A	United Kingdom and other countries Type G

4-3 Footswitch (REF: WB50402W, double pedal)

Classification	**Protection class according to IEC 60529**	IPX8 (except the plug section)
Size, weight and packaging	**Width x Depth x Height**	350 × 185 × 65 mm
	Weight of footswitch	1.9 kg
	Length of cord	4 m
	Weight of packaging	0.5 kg
	Type of packaging	Cardboard material

4-4 Footswitch (REF: WB50403W, single pedal, optional)

Classification	**Protection class according to IEC 60529**	IPX8 (except the plug section)
Size, weight and packaging	**Width x Depth x Height**	175 × 185 × 50 mm
	Weight of footswitch	1.6 kg
	Length of cord	4 m
	Weight of packaging	0.5 kg
	Type of packaging	Cardboard material

4-5 Neutral electrode cable "P-cord" (REF: MAJ-814, optional)

Size	**Weight**	0.14 kg
	Length of cord	3.1 m

4-6 Communication cable 0.25 m (REF: MAJ-1871, optional)

Size	**Weight**	0.05 kg
	Length of cord	0.25 m

4-7 Communication cable 10 m (REF: MAJ-1872, optional)

Size	**Weight**	0.5 kg
	Length of cord	10 m

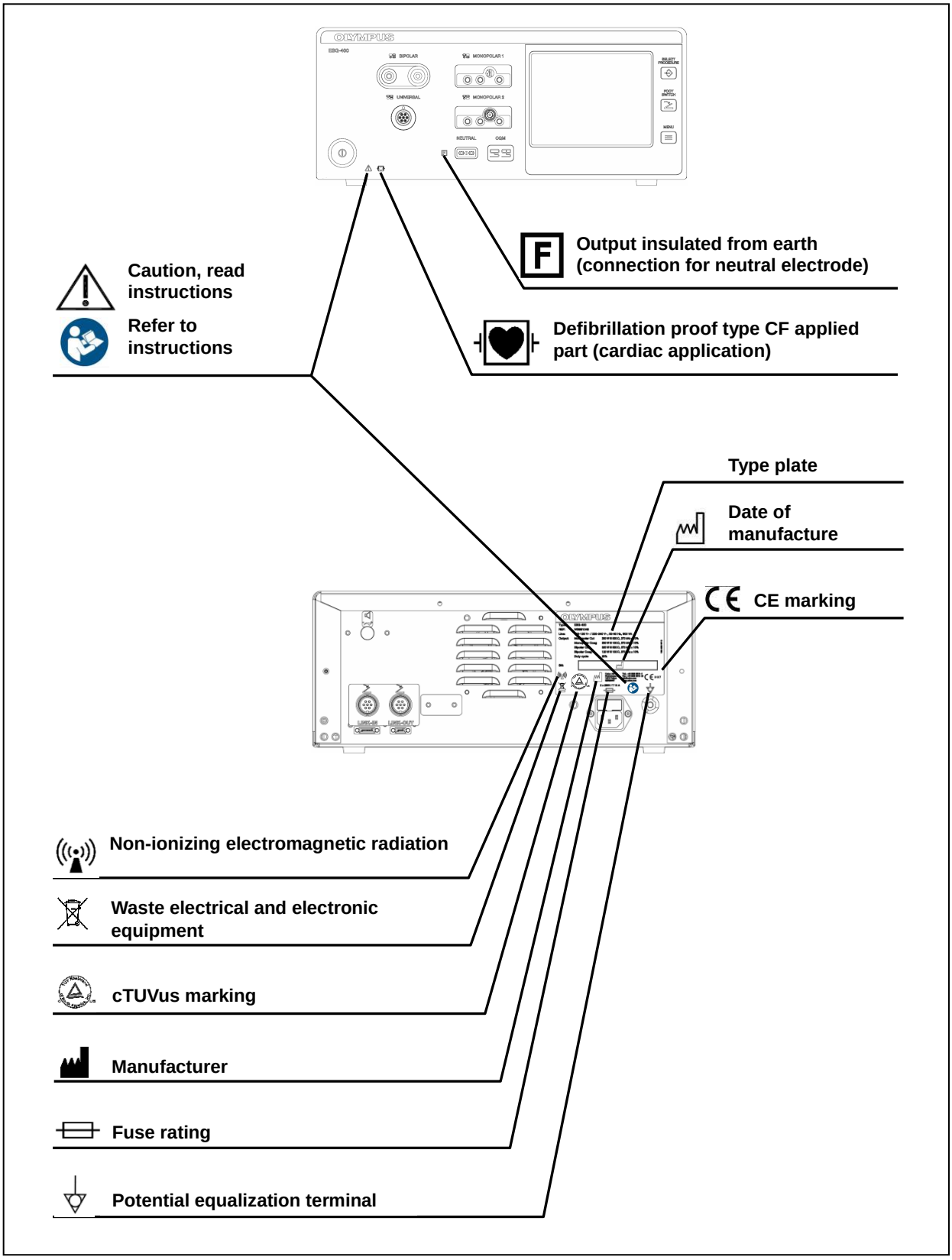
4-8 Adapter for UHI-2/3 (REF: MAJ-1873, optional)

Size	**Width x Depth x Height**	100 × 77 × 42 mm
	Weight	0.35 kg
Compatible cables		MAJ-1871, MAJ-1872

5 Name and Function of each part

5-1 Symbols and descriptions

5-1-1 Safety related symbols



5-1-2 Front panel

Power on / off

Neutral electrode – non-split type

Neutral electrode – split type

Select procedure

Footswitch

Menu

BIPOLAR socket

MONOPOLAR 1 socket

UNIVERSAL socket

MONOPOLAR 2 socket

5-1-3 Touch screen

Double footswitch

Single footswitch

Autostart

Plus

Minus

Return

OK

Cancel

Save procedure

Delete procedure

Languages

Touch tone on

Touch tone off

Software version

Safety test

Service

Volume

Brightness

Select procedure (in title line)

Menu (in title line)

Toggle

Previous

Next

Numeric

Alphabetic

Uppercase / lowercase

Backspace

Caution

Communication indicator

Reset

RCAP Resistance Controlled Automatic Power

Reference to BIPOLAR socket

Reference to MONOPOLAR 1 socket

Reference to UNIVERSAL socket

Reference to MONOPOLAR 2 socket

5-1-4 Rear panel

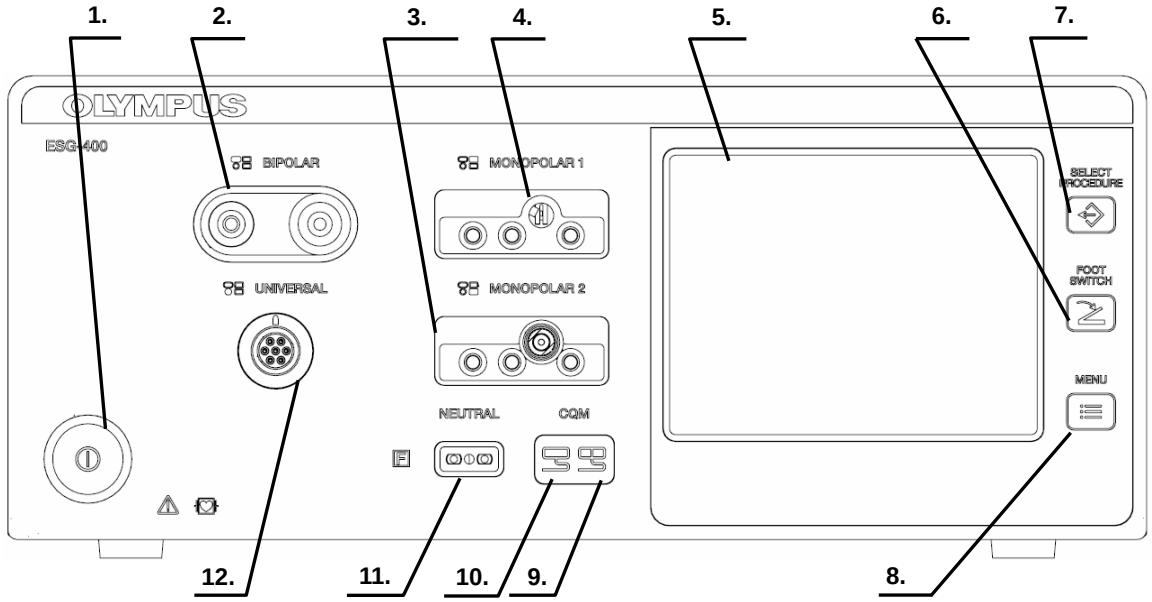
Volume

Footswitch

LINK-IN LINK-IN socket

LINK-OUT LINK-OUT socket

5-2 Front panel



1. **Power switch**
This switch turns the electrosurgical generator on and off.

2. **BIPOLAR socket**
This socket connects the plug of a bipolar HF instrument.

3. **MONOPOLAR 2 socket**
This socket connects the plug of a monopolar HF instrument.

4. **MONOPOLAR 1 socket**
This socket connects the plug of a monopolar HF instrument.

5. **Touch-screen**
Displays the connection status of the accessories and peripherals connected to the electrosurgical generator. It is also used to show and modify the output settings (e.g. mode, output power, effect) as well as to control other functions (e.g. save procedures, delete procedures).

6. **FOOTSWITCH push button**
This button is used to open the “Footswitch screen” to assign one or two footswitch(es) or the autostart function to a specific output socket.

7. **SELECT PROCEDURE push button**
This button is used to open the “Select Procedure screen” to recall saved settings.

8. **MENU push button**
This button is used to open the “Menu screen” to control several functions (save or delete a procedure, control the touch tone, output volume and brightness as well as other functions).

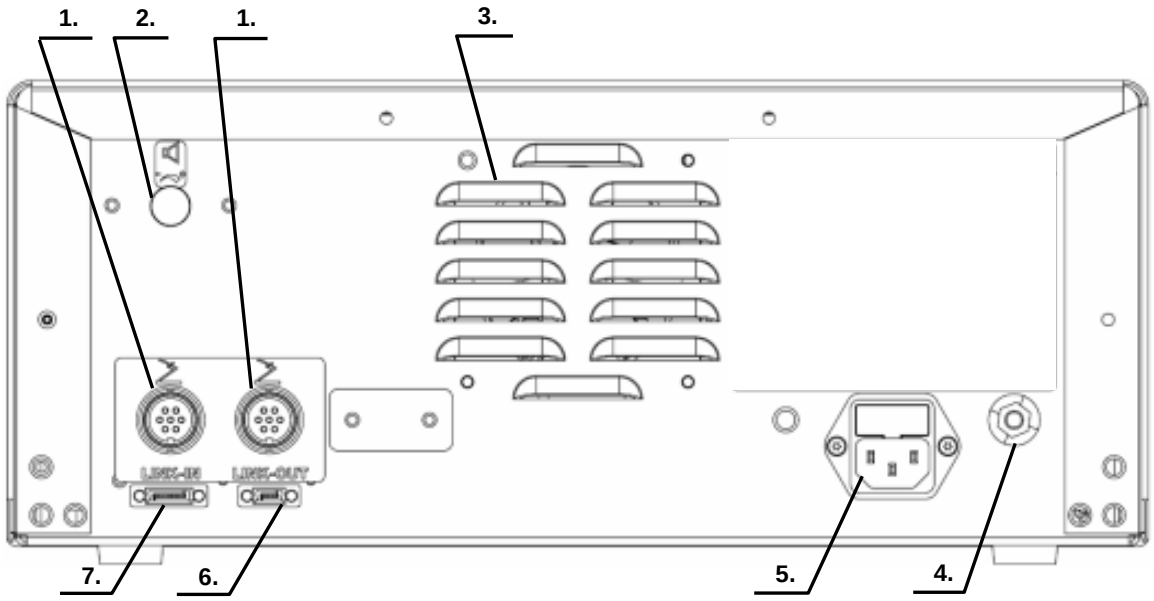
9. **Contact quality monitor indicator for split neutral electrode**
This indicator illuminates green if a split neutral electrode is connected and the contact resistance is within an acceptable range. The indicator illuminates red if the split neutral electrode is not connected or not applied properly (e.g. bad contact quality or partly dislocated) or no neutral electrode is connected (in both cases the activation of monopolar output is disabled).

10. **Contact quality monitor indicator for non-split neutral electrode**
This indicator illuminates green if a non-split neutral electrode is connected.

11. **Neutral electrode socket**
This socket connects the plug of a neutral electrode for monopolar application.

12. **UNIVERSAL socket**
This socket connects the plug of an Olympus HF instrument with HF instrument recognition.

5-3 Rear panel



1. **Footswitch sockets**
This socket connects the plug of a single or double pedal footswitch.

2. **Volume control**
This knob is used for adjusting the output volume.

3. **Ventilation hole**
Holes for air ventilation via a cooling fan; there are also ventilation holes on each side of the electrosurgical generator.

4. **Equipotential bonding point**
To increase electrical safety, this point is used for potential equalization. All equipment housings that come into contact with the patient are electrically connected in order to prevent low-frequency electrical currents from endangering the patient in the event of a defect in the conventional protective conductor system.

5. **AC power socket**
This socket serves as a connection to the mains power supply via a power cord

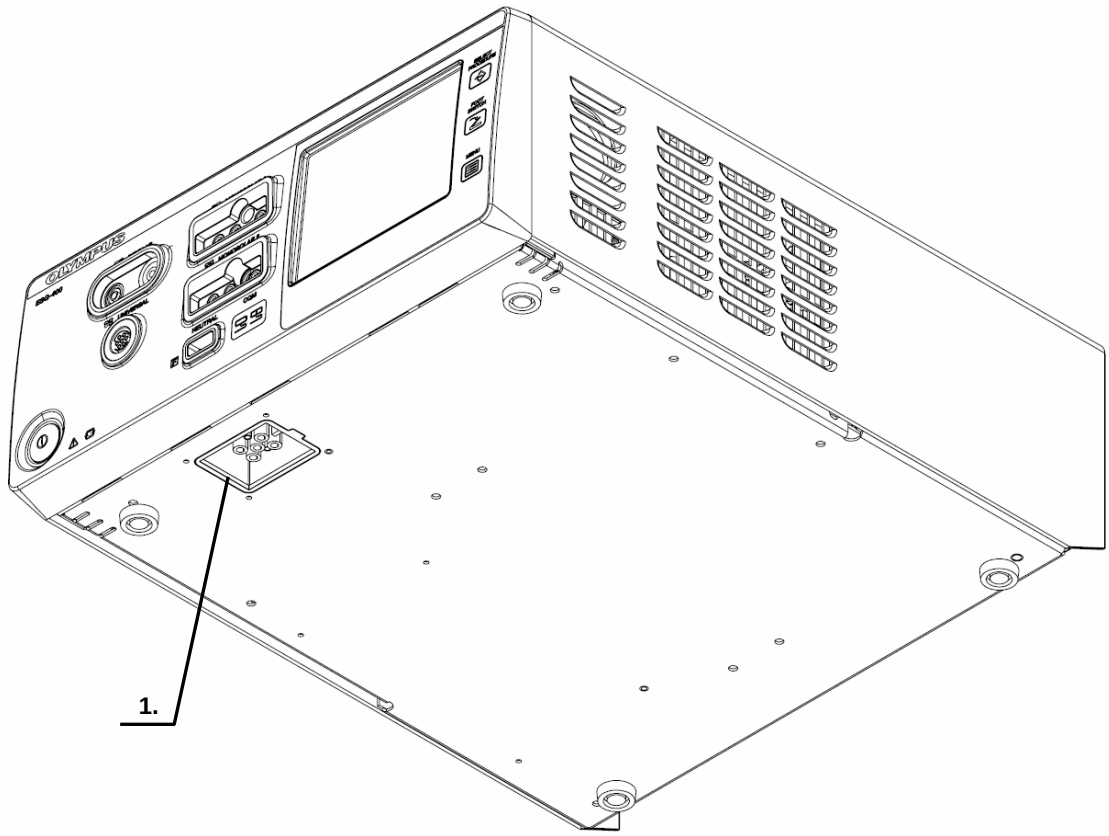
6. **LINK-OUT socket**
This socket connects the plug (14-pin) of a cable connected to peripheral equipment.

7. **LINK-IN socket**
This socket connects the plug (26-pin) of a cable connected to peripheral equipment.

NOTE

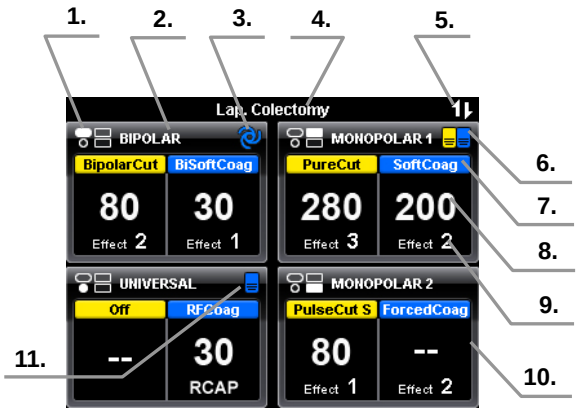
- The touch-screen messages may depend on the language setting of the electrosurgical generator.
- For a detailed explanation of the different types of sockets, refer to chapter 6 “Connection of neutral electrode” and chapter 3.7 “Connection of HF instruments”.

5-4 Bottom panel



1. **Docking socket**
This socket connects the plug (7-pin) of a docking connector to connect peripheral equipment. For more details, see chapter 1-6-1.

5-5 All screen



1. **Reference to output sockets indicator**
This indicator shows the corresponding output socket where the same symbol is printed on the front panel.

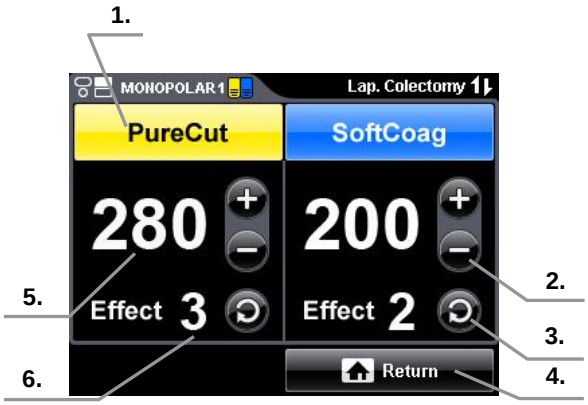
2. **Output socket name**
The name of the corresponding output socket is displayed here.

3. **Autostart indicator**
This symbol indicates if the autostart function is assigned to the corresponding output socket. Blank if

autostart or footswitch is not assigned. Refer to chapter 6.4, “Assign footswitch and autostart function”.

4. **Procedure name**
   The name of the selected procedure is displayed here. Blank if no procedure is selected.
5. **Communication indicator**
   This symbol indicates if communication with peripheral equipment connected to the docking socket is established.
6. **Footswitch indicator (double pedal)**
   This symbol indicates if a connected double pedal footswitch is assigned to the corresponding output socket. Blank if autostart or footswitch is not assigned. Refer to chapter 6.4, “Assign footswitch and autostart function”.
7. **Output mode**
   The name of the output mode as selected in the “Mode screen” is displayed here. If “Off” is selected, “--“ will be displayed instead of power level and effect.
8. **Output power level**
   The number shows the output power level as selected in the “Set screen”. If an output power level is set to zero, “--” will be displayed instead of numbers.
9. **Effect**
   The number shows the effect as selected in the “Set screen”. For RFCoag mode the RCAP function can be selected instead of an effect (refer to chapter 5.3, “Output setting”).
10. **Button area**
    Each button covers the entire area including all output socket related information as described above (3. to 10.). Press the button, to switch to the corresponding “Set screen” to select the mode, power levels and effects for the corresponding output socket.
11. **Footswitch indicator (single pedal)**
    This symbol indicates if a connected single pedal footswitch is assigned to the corresponding output socket. Blank if autostart or footswitch is not assigned. Refer to chapter 6.4, “Assign footswitch and autostart function”.

5-6 Set screen



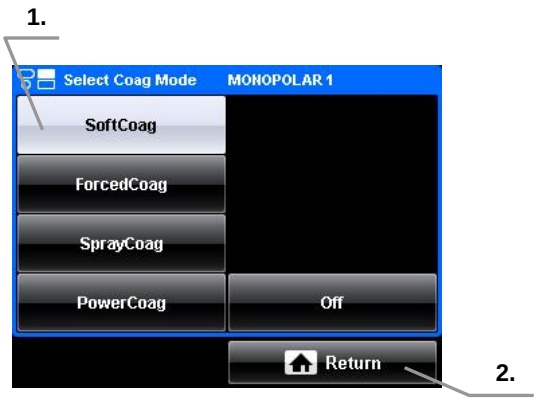
1. **Mode button**
   The name of the output mode as selected in the “Mode screen” is displayed here. Press this button to switch to the “Mode screen”. If “Off” is selected,
   “--“ will be displayed instead of power level and effect.
2. **Plus button / Minus button**
   These buttons increase / decrease the output power level.
3. **Toggle button**
   This button switches to the next effect.
4. **Return button**
   Press this button to save the settings and to return to the “All screen.”
5. **Output power level**

The number shows the selected output power level. If an output power level is set to zero, "--" will be displayed instead of numbers.

6. **Effect**

The number shows the selected effect. For RFCoag mode the RCAP function can be selected instead of an effect (refer to chapter 5.3, "Output setting")

5-7 Mode screen



1. **Mode button**

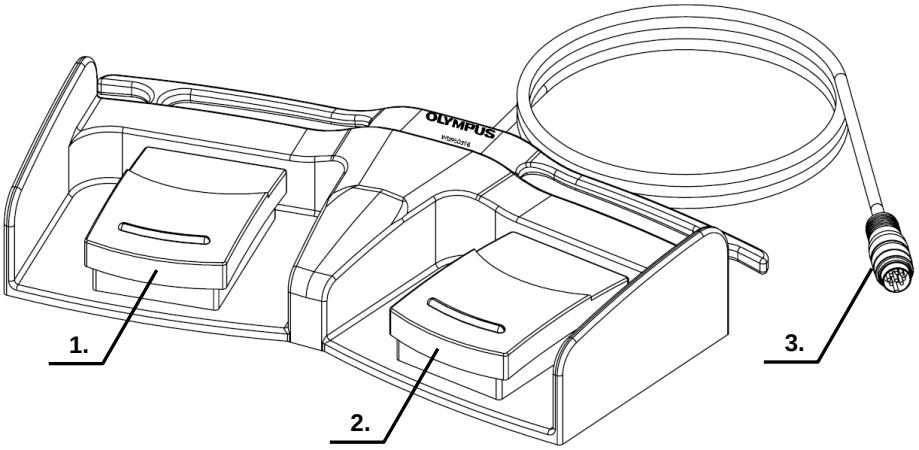
These buttons allow the mode selection for a corresponding output socket as shown in the title line. If a selection is already activated, this is indicated by a gray button. If no mode shall be selected, press the "Off button."

2. **Return button**

Press this button to return to the "Set screen."

5-8 Footswitch with two pedals

The footswitch with two pedals (Olympus REF: WB50402W) is included in delivery.



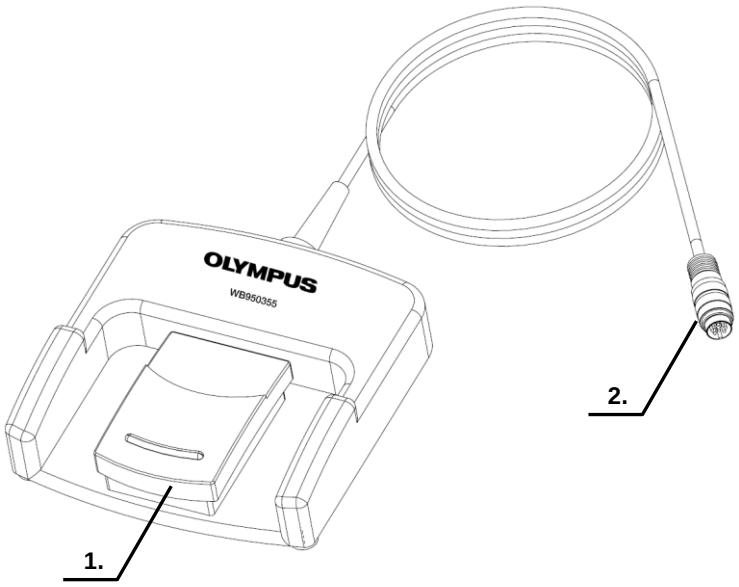
1. **Cut pedal (yellow color)**
This pedal is used to activate the selected cutting mode.

2. **Coagulation pedal (blue color)**
This pedal is used to activate the selected coagulation mode.

3. **Footswitch plug**
Connects the footswitch with the electrosurgical generator on the rear panel.

5-9 Footswitch with one pedal (optional)

The footswitch with one pedal (Olympus REF: WB50403W) is an optional item which may be purchased separately.

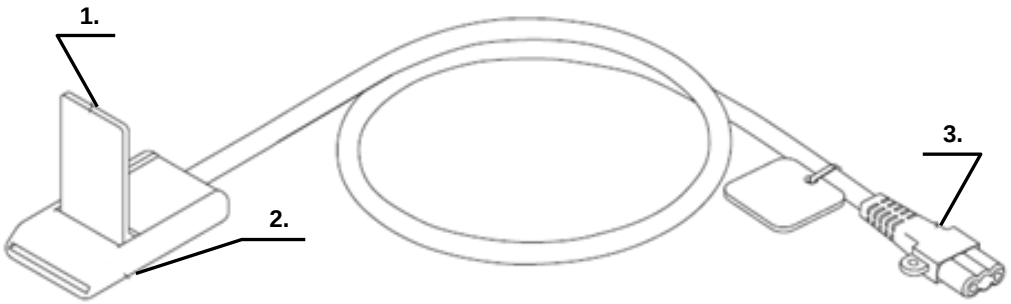


1. **Coagulation pedal (blue color)**
This pedal is used to activate the selected coagulation mode.

2. **Footswitch plug**
Connects the footswitch with the electrosurgical generator on the rear panel.

5-10 Neutral electrode cable “P-cord” (optional)

The neutral electrode cable “P-cord” (Olympus REF: MAJ-814) is an optional item for the connection with a neutral electrode which may be purchased separately.



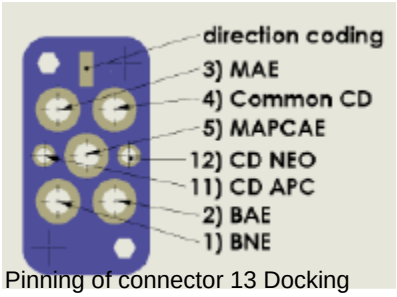
1. **Lever-locking arm**
This arm secures the connector of the neutral electrode with the clamp.

2. **Clamp**
This clamp connects the neutral electrode to the “P-cord”.

3. **Plug on the electrosurgical generator side**
This plug connects the “P-cord” to the electrosurgical generator.

6 Connector

6-1 Docking Connector



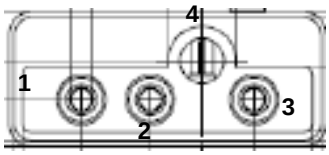
Pinning of connector 13 Docking Connector - view of connector side (bottom view) of ESG-400

1) BNE – Bipolar Neutral Electrode
2) BAE – Bipolar Active Electrode
3) MAE – Monopolar Active Electrode
4) Common CD – Common ground for connection detection
5) MAPCAE – Monopolar Active Electrode
11) CD APC – Active pin for connection detection
12) CD NEO – Active pin for connection detection

6-2 Monopolar Standard 1

Type: 3 pin Valleylab, pin diameter = 4mm
1 pin BOVIE, pin diameter = 8 mm

Function: Monopolar output
Finger switch input (only for Valleylab: cut and coag)

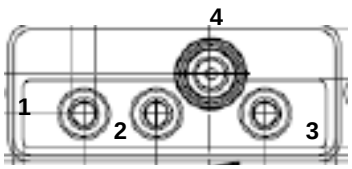


1 Hand Cut
2 Hand Coag
3 Active electrode
4 Active electrode

6-3 Monoploar Standard 2 (Erbe)

Type: 3 pin Valleylab, pin diameter = 4mm
Coaxial ERBE, pin diameter = 5 mm (inner) and 9 mm (outer)

Function: Monopolar output
Finger switch input (cut and coag)

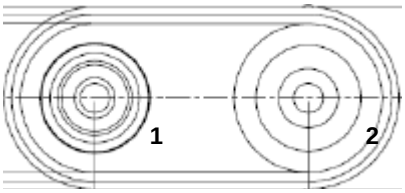


1 Hand Cut
2 Hand Coag
3 Active electrode
4 Cut+Coag+Active electrode (top)

6-4 Bipolar Standard 3

Type: 2 pin socket, pin diameter = 4mm / pin distance 28.8 mm
Coaxial socket, pin diameter = 4 mm (inner) and 8 mm (outer)

Function: Bipolar output

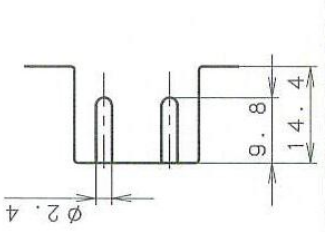


1 Neutral electrode
2 Active and neutral electrode

6-5 Monopolar Neutral Electrode

Type: 2 pins socket, Pin diameter = 2.5 mm, Pin distance = 10 mm

Function: Monopolar output
CQM input



Principle sketch of connector 5 Neutral Electrode

6-6 Foot switch 1 (SIP/SOP)

Type: Foot switch, 7-pol.

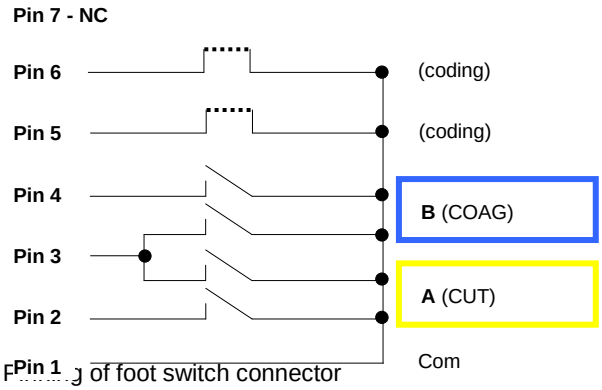
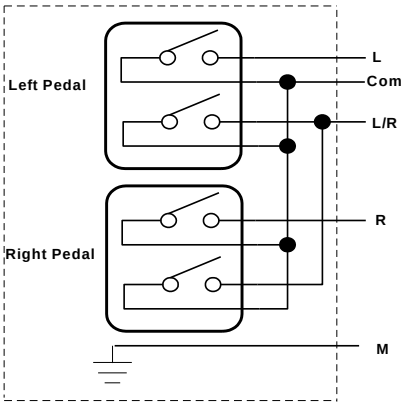


Figure of foot switch connector

6-7 Foot switch 2 (SIP/SOP)

Type: Foot switch, 7-pol.

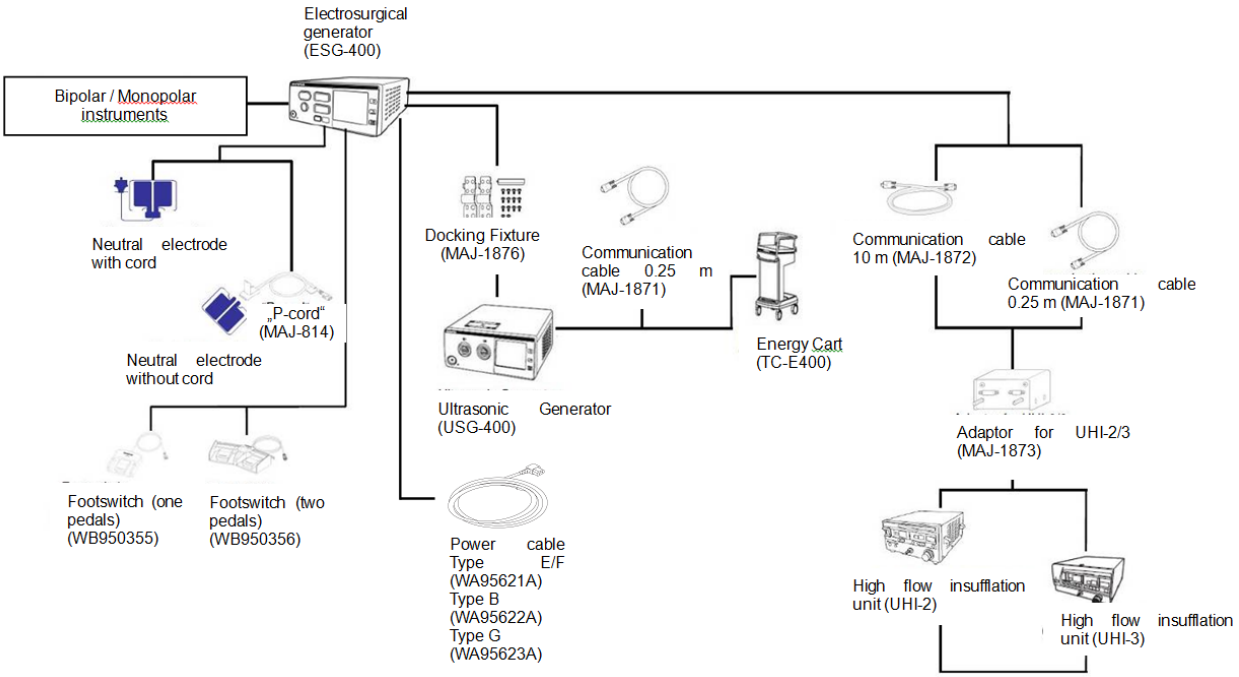


Activation detection of foot switch

7 System Diagram

The recommended combinations of ancillary equipment and accessories that can be used with the electrosurgical generator are listed in the system chart below. In addition, new products released after the introduction of this product may also become compatible with this electrosurgical generator. For further details, contact Olympus.

WARNING If combinations of equipment other than those shown below are used, the full responsibility is assumed by the medical treatment facility.


Electrosurgical generator (ESG-400)
Bipolar / Monopolar instruments
Neutral electrode with cord
„P-cord“ (MAJ-814)
Neutral electrode without cord
Footswitch (one pedals) (WB950355)
Footswitch (two pedals) (WB950356)
Docking Fixture (MAJ-1876)
Communication cable 0.25 m (MAJ-1871)
Energy Cart (TC-E400)
Ultrasonic Generator (USG-400)
Power cable Type E/F (WA95621A) Type B (WA95622A) Type G (WA95623A)
Communication cable 10 m (MAJ-1872)
Communication cable 0.25 m (MAJ-1871)
Adaptor for UHI-2/3 (MAJ-1873)
High flow insufflation unit (UHI-2)
High flow insufflation unit (UHI-3)

8 Cleaning, storage and disposal

The electrosurgical unit may be contaminated with infections materials, therefore, before servicing, perform the following cleaning procedures. For maintenance and storage of other items than those described below, refer to the respective instructions for use.

8-1 Cleaning

All surfaces of the unit's housing can be cleaned and disinfected with the cleaning agents and surface disinfectants normally used for medical equipment (mild cleaning solution, e.g. 70 % isopropyl alcohol). No liquid must enter the connector or the unit during cleaning.

1) Switch off the electrosurgical unit and disconnect the power cord from the grounded wall outlet.

2) If the equipment and / or accessories are contaminated with blood or other potentially infectious materials, first wipe off all gross debris using neutral detergent, and then wipe its surface with a lint-free cloth moistened with a surface disinfectant.

3) To remove dust, dirt and non-patient debris, wipe the electrosurgical unit and footswitch using a soft, lint-free cloth moistened with 70 % ethyl or isopropyl alcohol.

WARNING After cleaning the electrosurgical unit, dry it thoroughly before storage or using it again. If it is used while still wet, there is a risk of electric shock.

Patient debris and reprocessing chemicals are hazardous. During cleaning and disinfection, always wear appropriate personal protective equipment, such as eye wear, face mask, moisture-resistant clothing and chemical-resistant waterproof gloves that fit properly so that your skin is not exposed. Always remove contaminated protective clothing before leaving the reprocessing area.

CAUTION When disconnecting plugs of instruments or power cords, always hold the plug. Pulling the cable may result in damaging of the wires.

Never immerse the electrosurgical unit in water, clean or disinfect by immersion, gas sterilization or autoclaving. It may cause equipment damage.

Do not clean the connectors or the alternating current power inlet. Cleaning them can deform or corrode the contacts, which could damage the electrosurgical unit.

Do not wipe the external surface with hard or abrasive wiping material. The surface will be scratched.

8-2 Storage

Before storage of the electrosurgical unit, disconnect the power cord and store it properly according to the environmental conditions described in chapter 1.4 (Technical data).

CAUTION Do not store the electrosurgical unit in a location exposed to direct sunlight, x-rays, radioactivity, liquids or strong electromagnetic radiation (e.g. near microwave medical treatment equipment, short-wave medical treatment equipment, magnetic resonance imaging equipment, radio or mobile phones). Damage to the electrosurgical unit may result.

8-3 Disposal of the unit

When disposing of this electrosurgical unit, or any of its components (such as fuses), follow all applicable national and local laws and guidelines.

Waste electrical and electronic equipment

In accordance with European Directive 2002/96/EC on waste electrical and electronic equipment (WEEE), the product must not be disposed of as unsorted municipal waste, but should be collected separately.

Refer to Olympus for return and / or collection systems available in your country.

CHAPTER 2: BLOCK DESCRIPTION

1 BLOCK DESCRIPTIONS 38
1-1 Motherboard 39
1-2 HVPS Board 41
1-3 Generator board 41
1-4 Relay Board 41
1-5 Front Panel 42

1 Block Descriptions

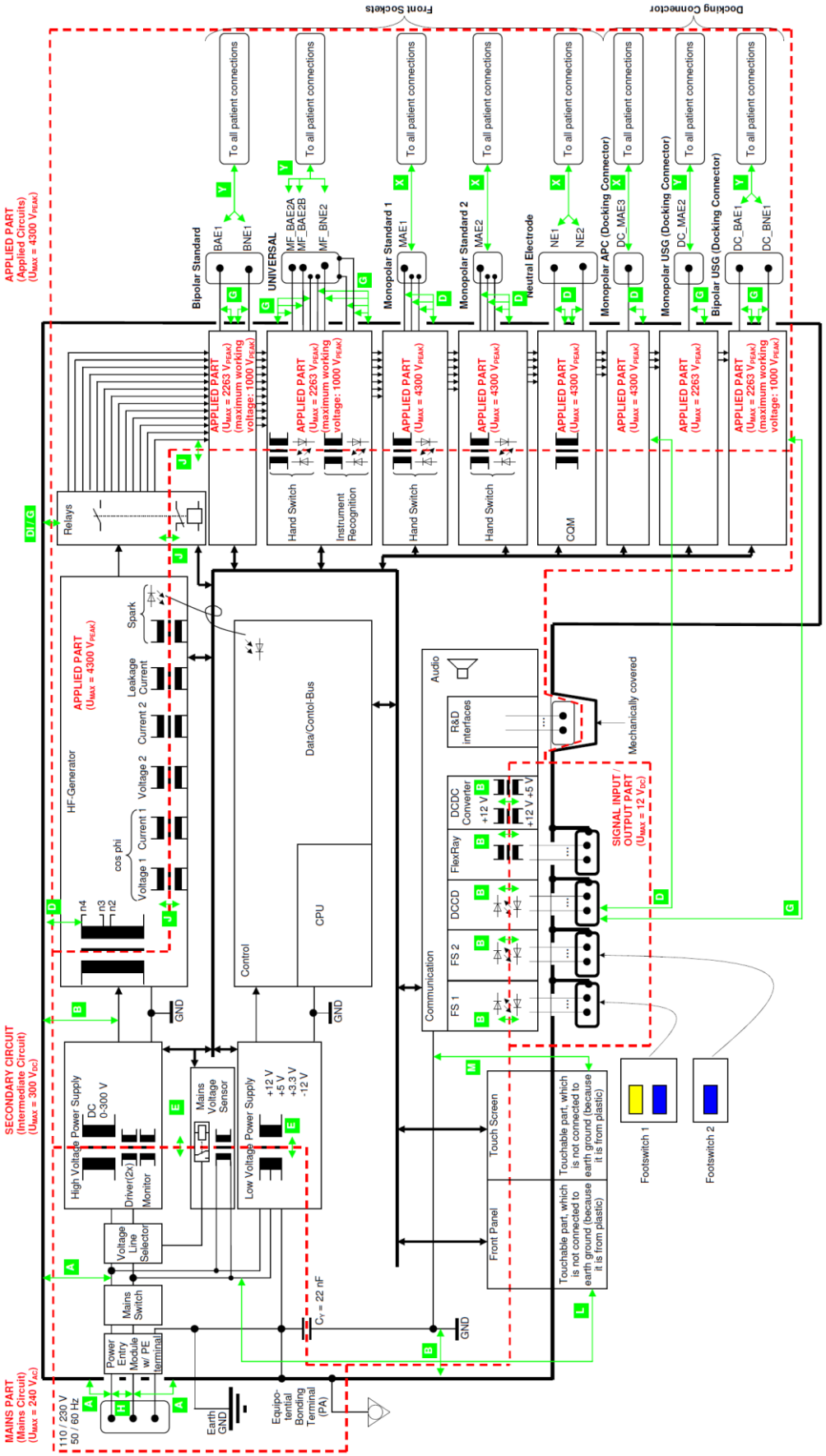


Fig. 2.1.1. Block descriptions

1-1 Motherboard

Due to the containing embedded PC the Motherboard is the central unit of the ESG-400. The Motherboard controls the Relay Board, the HVPS Board and the Generator Board. It contains all input and output interfaces to the user as well as to other medical devices or computers. Additionally functionalities off the board are the low voltage supplies for the complete unit, the mains input including filters and the measuring part of the voltage line selection circuit for switching between 115 and 230 VAC.

Overview:

- Embedded PC incl. periphery
- Embedded PC with MPC5200 controller (incl. address and data bus, chip selects, interrupt inputs, I2C, SPI, in-/output ports, uarts, timer)
- Watchdog circuit
- Chip select decoder
- Hardware reset
- JTAG interface
- Real time clock
- POF interface for the spark monitor
- Digital input and output circuits
- D/A converters for controlling the HVPS
- A/D converters for measuring different signals from Relay, HVPS and Generator, temperatures and watching on important voltages

Connections/Interfaces:

- To the PCBs Relay, HVPS and Generator
- Push buttons for user inputs on the front panel
- Volumeboard for changing the speaker volume
- Power Indicator shows power-on of the unit on the front
- CQM Indicator shows status of CQM on the front
- Controlling and driving the main housing fan
- Audio circuit incl. D/A converter and amplifier for sound
- Graphic controller with driver and backlight for the front display
- Touch controller for the touch display
- Ethernet controller and connector for external connections
- RS-232 with connector for external connections
- USB host with transceiver and connector for external connections
- FlexRay controller, transceiver and connector for external connections
- Connectors for footswitch incl. detection and analysis circuit
- Connectors for handswitches incl. activation detection circuits
- Instrument recognition circuit for instruments connected to the universal socket
- Detection circuit for devices connected to the docking connector

Low voltage supplies

- Switching regulators for -12 VDC, +5 VDC and +3,3 VDC (5 V and 3,3 V cascaded)
- DC/DC converters for isolated +12 VDC and +5 VDC SIP/SOP voltages
- Batteries for a permanent +3 V voltage for RTC and SRAM
- Reference voltage of 8,192 V

Mains input

- Input filters
- Inrush current limiter
- Mains voltage measurement and output signal for a selection circuit on the HVPS

1-2 HVPS Board

The high voltage power supply (HVPS) is a switching mode power supply with series resonance circuit. It provides a high DC voltage for the HF Generator. It contains:

- voltage line selection circuit, for automatic change between 110/230 VAC
- simple rectifier circuit
- PWM driving circuit
- driving circuits including a digital flip-flop stage for complete cycle driving
- power FET half-bridge, a series resonance circuit, output transformer and rectifying stage
- current and voltage monitors
- discharge circuit

1-3 Generator board

The Generator Board generates the HF output energy from a DC input voltage and contains:

- control circuit for generating start and driving pulses of “one cycle” sinus oscillator
- driving stage for power FET, parallel resonance circuit and series resonance circuit
- relays for switching between different transformer windings
- HF output voltage monitor and redundant HF voltage monitor
- HF output current monitor and redundant HF current monitor
- HF output phase monitor
- HF leakage current monitor
- spark monitor (SPM) supply circuit
- spark monitor for detecting positive and negative DC voltage offset

1-4 Relay Board

The Relay board is used to connect the active output socket to the generator board. It contains:

- connectors to every single HF output socket
- relays which are separating the non active output terminals from the active output terminals
- separating relays are forced guided relays with read-back contact in secondary circuit to control the relay status
- contact quality monitor (CQM)
- transient voltage suppression (TVS) diodes in applied part

1-5 Front Panel

The Front Panel is the main part of the user interface. It contains:

- LCD touch screen
- Push Buttons
- Contact Quality Monitor
- BIPOLAR socket
- MONOPOLAR 1 socket → Valleylab & Bovie
- MONOPOLAR 2 socket → Valleylab & Erbe
- UNIVERSAL socket
- Socket for neutral electrode

CHAPTER 3: REPAIR SYSTEM

1 ESG-400 MAIN UNIT 44
2 BOARD COMPATIBILITY 44
3 OPTIONAL ACCESSORIES 44
3-1 WB50402W (Footswitch with two pedals) 44
3-2 WB50403W (Footswitch with one pedal) 44
3-3 MAJ-814 (Neutral electrode cable “P-cord”) 44
4 PRECAUTIONS ON FUNCTION AND OPERATION SETTINGS 44
4-1 General Precautions 44

1 ESG-400 Main Unit

(1) In general, the main unit must be shipped to a service center in the event of a malfunction.

(2) Individual units can be replaced.

2 Board Compatibility

The compatibility of boards and components is dependent on the hardware version of the generator. The hardware version can be indentified by the serial number of the generator.

The serial number starting with 5 numbers, hardware version with WXX and followed by 3 numbers after the hyphen.

Example: XXXXX**WYY**-ZZZ, WYY will show the hardware version.

3 Optional Accessories

3-1 WB50402W (Footswitch with two pedals)

Supplied as a spare part subject to repair services in the event of a malfunction.

3-2 WB50403W (Footswitch with one pedal)

Supplied as a spare part subject to repair services in the event of a malfunction.

3-3 MAJ-814 (Neutral electrode cable “P-cord”)

Supplied as a spare part subject to repair services in the event of a malfunction.

4 Precautions on Function and Operation Settings

4-1 General Precautions

Before repair, it is generally advisable to record the function and operation settings as the basis for restoring these settings after service.
If the original settings cannot be known due to mechanical problems present at the time the unit was accepted for repair, apply the factory-set values or the safest settings (such as the lowest output levels). In this case, inform the user that the settings have been changed.

CHAPTER 4: TROUBLESHOOTING

1 GENERAL 46
2 NEUTRAL ELECTRODE OPERATION 47
3 ERROR SCREEN, CODES AND MEASURES 48
3-1 What to do when no error code is displayed 50
3-2 What to do when an error code is displayed 54

1 General

If the electrosurgical unit has visible damage, do not use the electrosurgical unit and contact the legal manufacturer. If the unit is not functioning properly, use the information in this chapter to identify and correct the malfunction. If the problem cannot be resolved by the described remedial action, stop using the electrosurgical unit and contact the legal manufacturer for repair.

DANGER Never use the electrosurgical unit if an abnormality is suspected.

CAUTION Repairs must only be carried out by Olympus or a firm authorized by Olympus.

CAUTION Preventive maintenance (inspection / periodic safety check) must only be carried out by a qualified person / technician.

2 Neutral electrode operation

Check the following table, to identify or correct failures regarding the neutral electrode operation.

Contact quality monitor	Mode	Indication
Bipolar application	**Standby and activation**	 A neutral electrode is not required. Contact quality monitor indicator for split neutral electrode illuminates red.
Monopolar application	A non-split neutral electrode is connected. **Activation is possible.** Contact quality monitor detects connection of neutral electrode. **If a split neutral electrode is connected, it has a short circuit. Immediately replace the neutral electrode!**	 Contact quality monitor indicator for non-split neutral electrode illuminates green.
	A split neutral electrode is connected. **Activation is possible.** Contact quality monitor detects connection of neutral electrode and contact to patients' skin.	 Contact quality monitor indicator for split neutral electrode illuminates green.
	During standby: A split or a non-split neutral electrode is not connected or a split neutral electrode detaches. **Activation is disabled.** **During activation:** A split or a non-split neutral electrode has disconnected or a split neutral electrode detaches. **The activation is stopped.**	 Contact quality monitor indicator for split neutral electrode illuminates red. During activation an alarm signal can be heard and the touch-screen will display an error window (E202).

Legend: Red illumination of the indicator

Green illumination of the indicator

3 Error screen, codes and measures

Follow the troubleshooting advices in this chapter, to identify or correct failures. The error window is configured as shown in figure below.

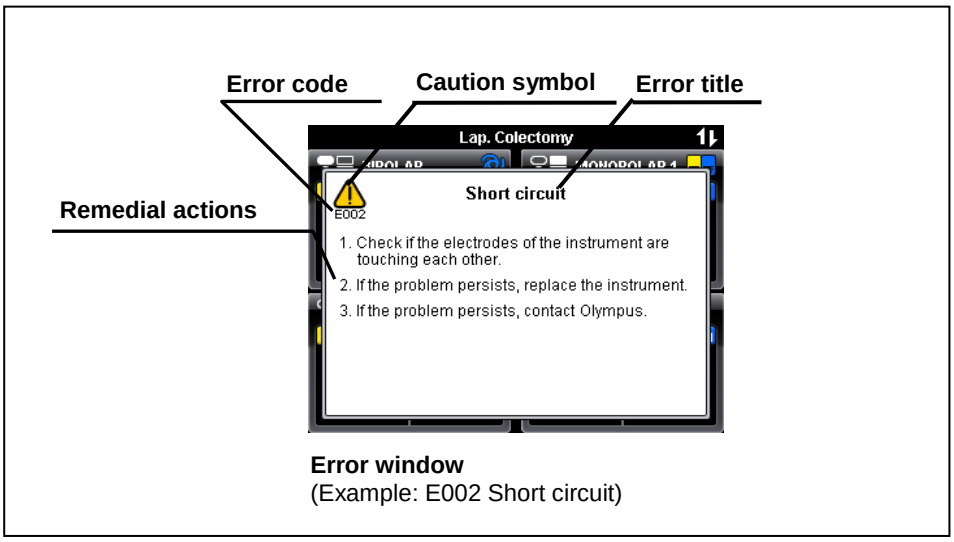


Fig. 4.3.1. Error Screen

If an error occurs (see Fig. 4.3.1):

- An error window will appear and an alarm signal is audible.
- A short message with the error code, error title and a description of the remedial action will be displayed.
- The error code consists of an error number shown under the “caution” symbol.
- Depending on the error priority, the condition of the audible signal and the “caution” symbol are different (see Table 4.1).
- Proceed with the described remedial action.
- The error window disappears after a few seconds, if the error is cleared.
- If the error window is still displayed, the error is not cleared. Proceed with the next remedial action if available.

Error category	Error condition priority	Indicator (“caution”) symbol condition
High priority	Immediate user response is required	Flashes in red color
Medium priority	Prompt user response is required	Flashes in yellow color
Low priority	Awareness of the user is required	Constant on in yellow color

Table 4.1: Error priorities and the corresponding indicator symbol condition

NOTE

The electrosurgical generator is equipped with an intelligent alarm system which determines alarm conditions on the base of multiple variables. Depending on the risk potential, alarms are classified in “high priority”, “medium priority” and “low priority” alarms. An alarm of higher priority overrides an existing alarm of lower priority. If more than one alarm situation of equal priority is determined, the one that occurred first is displayed only. This electrosurgical generator complies with the IEC 60601-1-8: 2006.

3-1 What to do when no error code is displayed

Perform the indicated remedial actions below. If the problem cannot be resolved by the described remedial action, contact the legal manufacturer.

Situation	Possible cause	Remedial action
The electrosurgical generator does not respond after pressing the power switch.	Improper connection of the power cord to the AC power socket on the rear panel of the electrosurgical generator or to the grounded wall outlet.	Check the power cord and the grounded wall outlet for correct connection.
	The grounded wall outlet has wrong or not output voltage.	Check the grounded wall outlet or use an alternative grounded wall outlet.
	The power cord is damaged.	Check the power cord for damages and, if necessary, replace the power cord.
	Malfunction of the electrosurgical generator.	Contact the legal manufacturer.
The touch-screen remains dark after switching the electrosurgical generator on (sound is audible after switching on).	Malfunction of the touch-screen.	Contact the legal manufacturer.
The touch-screen cannot be controlled.	An object is in contact with the touch-screen.	Remove the object.
	The touch-screen is not properly calibrated.	Contact the legal manufacturer.
	Malfunction of the touch-screen.	Stop using the electrosurgical generator and press the power switch to turn off the electrosurgical generator. Contact the legal manufacturer.
The electrosurgical generator does not react when a push button on the front panel is pressed during standby.	A push button is already pressed.	Release the push button.
	Malfunction of the electrosurgical generator.	Contact the legal manufacturer.
The electrosurgical generator does not react when a (push) button on the front panel is pressed during activation.	The (push) buttons are not available during activation.	Release the footswitch or hand switch to stop the activation.

Situation	Possible cause	Remedial action
No sound is audible during activation.	The volume is set to an inaudible level (e.g. due to high environmental noise).	Increase the volume either on the touch-screen within the “Menu screen” or use the volume control on the rear panel of the electrosurgical generator.
	Malfunction of the electrosurgical generator.	Stop using the electrosurgical generator and press the power switch to turn off the electrosurgical generator. Contact the legal manufacturer.
The volume can not be adjusted via the volume control within the “Menu screen” or at the rear panel.	The volume of the error-related audible signal is not adjustable.	No action required.
	Malfunction of the electrosurgical generator.	Contact the legal manufacturer.
The electrosurgical generator does not respond to footswitch or handswitch activation.	Improper connection of the footswitch to one of the footswitch sockets on the rear panel of the electrosurgical generator or the HF instrument to the output socket.	Check the footswitch and the HF instrument for correct connection.
	The footswitch or the handswitch of the HF instrument and / or the connection cable are damaged.	Check the footswitch or the handswitch of the HF instrument and / or the connection cable for damages and, if necessary, replace the footswitch, the HF instrument or the connection cable.
	The incorrect footswitch pedal or handswitch button is pressed.	Press the correct footswitch pedal or handswitch button of the HF instrument.
	The electrosurgical generator is not switched on.	Switch on the electrosurgical generator with the power switch.
	Another footswitch pedal or handswitch button of the HF instrument is pressed.	To activate the intended output, release the current pressed footswitch pedal or handswitch button of the HF instrument.
	The output is activated by the peripheral equipment.	If the output of the peripheral equipment is activated, the output of the electrosurgical generator cannot be activated simultaneously. Stop using the peripheral equipment.
	A window is displayed on the touch-screen.	Press the “OK button” or “Cancel button” to close the window or wait until the window disappears automatically after a few seconds.
	The “All screen” or “Set screen is not displayed on the touch-screen.	Return to the “All screen” or “Set screen”.
	The corresponding output mode has been deactivated in the “Mode screen” (“Off” is displayed) or the power level has been set to “--“.	Select an output mode in the “Mode screen” or increase the power level via the “Set screen” (refer to chapter 5.3, “Output setting”).
	Malfunction of the electrosurgical generator.	Contact the legal manufacturer.
If the autostart function is selected, the electrosurgical	The autostart function is assigned to another output socket.	Check the correct assignment of the autostart function (refer to chapter 6.4, “Assign footswitch and autostart function”).

Situation	Possible cause	Remedial action
generator does not activate the output when the electrode has contact with the tissue.	Long time delay of the autostart function has been selected in the “Autostart screen”.	Set a shorter time delay in the “Autostart screen” (refer to chapter 6.5, “Menu - Autostart setup”).
	Malfunction of the electrosurgical generator.	Contact the legal manufacturer.
If an HF instrument is connected to the UNIVERSAL socket, the electrosurgical generator does not recognize the connected HF instrument.	Improper connection of the Olympus HF instrument plug with the UNIVERSAL socket on the front panel of the electrosurgical generator.	Check the Olympus HF instrument plug for correct connection.
	The HF instrument does not support Olympus HF instrument recognition.	Confirm the use of an Olympus HF instrument with HF instrument recognition capabilities.
	The Olympus HF instrument and / or the connection cable is damaged.	Replace the Olympus HF instrument and / or the connection cable.
	Malfunction of the electrosurgical generator.	Contact the legal manufacturer.
Footswitch or handswitch of the HF instrument is pressed and activation sound is audible but no output power is delivered.	The footswitch is assigned to another output socket.	Check the correct assignment of the footswitch (refer to chapter 6.4, “Assign footswitch and autostart function”).
	Improper connection of the HF instrument plug with the output socket on the front panel of the electrosurgical generator.	Check the HF instrument plug for correct connection.
	Malfunction of the electrosurgical generator.	Contact the legal manufacturer.

Situation	Possible cause	Remedial action
No output power is delivered when RFCoag mode with or without RCAP is selected and end of activation signal is audible.	The electrode has no contact with the tissue.	Check that the electrode has contact with the tissue.
	Improper connection of the HF instrument plug with the output socket on the front panel of the electrosurgical generator.	Check the HF instrument plug for correct connection.
	Damaged HF instrument connection cable.	Replace the HF instrument connection cable.
	Malfunction of the electrosurgical generator.	Contact the legal manufacturer.
The output of the electrosurgical generator cannot be deactivated.	The autostart function is selected to the current used output socket and both electrodes touch the tissue.	Remove the electrode from the tissue.
	Malfunction of the footswitch or handswitch.	Immediately switch off the electrosurgical generator by pressing the power switch. Replace the footswitch or HF instrument with handswitch.
	Malfunction of the electrosurgical generator.	Contact the legal manufacturer.
The electrosurgical generator cannot be switched off.	Malfunction of the electrosurgical generator.	Disconnect the power cord plug from the AC power socket on the rear panel of the electrosurgical generator or from the grounded wall outlet. Contact the legal manufacturer.
Automatic mist & smoke evacuation system/function does not work.	The settings are erroneous.	Correct the settings of the compatible high flow insufflation unit.
	The communication cable is not connected.	Connect the communication cable. Refer to 3.5, “Automatic mist & smoke evacuation system/function (when using the compatible high flow insufflation unit)”.
	The connection of the communication cable is erroneous.	Reconnect the communication cable. Refer to Section 3.5, “Automatic mist & smoke evacuation system/function (when using the compatible high flow insufflation unit)”.
	Compatible high flow insufflation unit malfunction.	Contact Olympus.

3-2 What to do when an error code is displayed

If an error code is displayed, perform the indicated remedial actions below. If the problem cannot be resolved by the described remedial action, contact the legal manufacturer.

Error no.	Error message	Possible cause	Remedial action
E001	**Open circuit**	Electrodes of the HF instrument may have no proper tissue contact.	Ensure that the electrodes of the HF instrument have proper tissue contact.
		Malfunction of the HF instrument and / or the connection cable.	Replace the HF instrument and / or the connection cable.
E002	**Short circuit**	Electrodes of the HF instrument may touch each other.	Ensure that the electrodes of the HF instrument do not touch each other.
		Malfunction of the HF instrument and / or the connection cable.	Replace the HF instrument and / or the connection cable.
E003	**---**	DockingConnectorError	---
E004	**Error**	Internal software error.	Send back to Olympus Service
E006	**Non-conductive fluid**	Use of non-conductive fluid during a bipolar cutting procedure. The active and / or neutral electrode is within an air environment.	Ensure that conductive fluid is used during bipolar resection procedure. Always immerse the active and / or neutral electrode within the conductive fluid.
		The bipolar Olympus HF instrument has not been properly connected to the UNIVERSAL socket or damaged connection cable.	Check the connection of the bipolar Olympus HF instrument to the connection cable and the connection of the connection cable to the UNIVERSAL socket and / or replace the connection cable.
		The electrode might be contaminated and encrusted.	Check the electrodes for contamination and encrustation before use and, if necessary, clean the electrodes.
E007 […] E011	**Error**		Refer to E004
E012	**Adjustment incomplete**	Adjustment missing or incomplete.	Complete the adjustment of the device.
E013 E014 E015	**Error**		Refer to E004
E016	**Burn-in incomplete**	Burn-in missing or incomplete.	Complete the burn-in of the device.

Error no.	Error message	Possible cause	Remedial action
E017	**Error**	Wrong or broken Footswitch, damaged hardware.	1. Check the Footswitch connection. 2. Change the Footswitch. 3. Send back to Olympus Service
E018	**Error**		Refer to E004
E019	**Footswitch combination**	Two single pedal or two double pedal footswitches have been connected.	Ensure that only one single pedal and/or only one double pedal footswitch are connected.
E020 E021 E022	**Error**	Internal hardware error.	Send back to Olympus Service
E023	**Invalid serial number**	Wrong or missing serial number of the device.	Send back to factory.
E024 […] E030	**Error**		Refer to E004
E031 E032	**Error**	Wrong docking connector coding signal, broken hardware.	1. Check the docking connection to the USG-400. 2. Send back to Olympus Service
E033 E034	**Error**		Refer to E020
E035 E036 E037	**Error**		Refer to E004
E038	**Error**	Internal hardware error.	Send back to Olympus Service
E039 […] E043	**Error**		Refer to E004
E045 […] E057	**Error**	Communication error with USG-400 or other devices.	1. Check the FlexRay connections. 2. Check if all other devices are working properly. 3. Send back to Olympus Service
E058 E059 E060	**Error**	Internal software or hardware error.	Send back to Olympus Service
E061 […] E066	**Error**		Refer to E004
E067 […] E081	**Error**		Refer to E045
E082 E083 E084	**Error**		Refer to E004
E085 […] E099	**Error**	Internal hardware error.	Send back to Olympus Service
E100 E101	**Error**	Spark Monitor communication	Send back to Olympus Service

Error no.	Error message	Possible cause	Remedial action
		error.	
E102	**Error**		Refer to E085
E103	**Push button pressed**	A push button on the Front Panel is pressed while switching on.	Release the push button.
E104	**Footswitch pedal pressed**	A pressed Cut Pedal on Footswitch 1 has been detected during power-up.	Release the Cut Pedal on Footswitch 1 and restart the device.
		Malfunction of the footswitch.	Change the Footswitch 1.
E105	**Footswitch pedal pressed**	A pressed Coag Pedal on Footswitch 1 has been detected during power-up.	Release the Coag Pedal on Footswitch 1 and restart the device.
		Malfunction of the footswitch.	Change the Footswitch 1.
E106	**Footswitch pedal pressed**	A pressed Cut Pedal on Footswitch 2 has been detected during power-up.	Release the Cut Pedal on Footswitch 2 and restart the device.
		Malfunction of the footswitch.	Change the Footswitch 2.
E107	**Footswitch pedal pressed**	A pressed Coag Pedal on Footswitch 2 has been detected during power-up.	Release the Coag Pedal on Footswitch 2 and restart the device.
		Malfunction of the footswitch.	Change the Footswitch 2.
E108	**Handswitch pressed**	A pressed Cut Handswitch at the Monopolar 1 socket has been detected during power-up.	Release the Cut Handswitch at the Monopolar 1 socket and restart the device.
		Malfunction of the HF instrument.	Replace the HF instrument.
E109	**Handswitch pressed**	A pressed Coag Handswitch at the Monopolar 1 socket has been detected during power-up.	Release the Coag Handswitch at the Monopolar 1 socket and restart the device.
		Malfunction of the HF instrument.	Replace the HF instrument.
E110	**Handswitch pressed**	A pressed Cut Handswitch at the Monopolar 2 socket has been detected during power-up.	Release the Cut Handswitch at the Monopolar 2 socket and restart the device.
		Malfunction of the HF instrument.	Replace the HF instrument.
E111	**Handswitch pressed**	A pressed Coag Handswitch at the Monopolar 2 socket has been detected during power-up.	Release the Coag Handswitch at the Monopolar 2 socket and restart the device.
		Malfunction of the HF instrument.	Replace the HF instrument.
E112	**Handswitch pressed**	A pressed Cut Handswitch at	Release the Cut Handswitch at the

Error no.	Error message	Possible cause	Remedial action
		the Multifunction socket has been detected during power-up.	Multifunction socket and restart the device.
		Malfunction of the HF instrument.	Replace the HF instrument.
E113	**Handswitch pressed**	A pressed Coag Handswitch at the Multifunction socket has been detected during power-up.	Release the Coag Handswitch at the Multifunction socket and restart the device.
		Malfunction of the HF instrument.	Replace the HF instrument.
E114	**Touch-screen pressed**	The screen is touched while switching on.	Release the finger from the screen.
E115	**Application time limit exceeded**	The maximum time limit for the application has been exceeded.	Release the footswitch or handswitch for about 15 sec. and activate again by repressing the footswitch or handswitch.
E116 […] E130	**Error**		Refer to E004
E131	**Unknown instrument**	An Olympus HF instrument has not been properly connected to the UNIVERSAL socket.	Check the connection of the Olympus HF instrument to the UNIVERSAL socket.
		Invalid default mode detected at the instrument connected to the Multifunction socket.	Change the Instrument at the Multifunction socket
E132	**Error**	Internal hardware error.	Send back to Olympus Service
E133	**Error**	Internal hardware error.	Send back to Olympus Service
E134	**Error**	Internal hardware error.	Send back to Olympus Service
E135	**Single pedal footswitch not assigned**	The single pedal footswitch has not been assigned to the corresponding output socket.	Assign the single pedal footswitch.
E136	**Double pedal footswitch not assigned**	The double pedal footswitch has not assigned to the corresponding output socket.	Assign the double pedal footswitch.
E137	**Error**	The Auto Start feature is not assigned correctly.	Reassign the Auto Start feature.
E138	**Error**	Invalid Thunder Beat mode setting detected.	1. Check the Thunder Beat instrument connected to the USG-400.
			2. Check the USG-400.
E139	**Error**	Invalid Thunder Beat seal mode setting detected.	1. Check the Thunder Beat instrument connected to the USG-400.
			2. Check the USG-400.
E140	**No mode selected**	No mode has been selected while activating.	Select a mode via the “Mode screen”.
E141	**Power set to zero (--)**	The power level for the chosen	Increase the power level via the “Set

Error no.	Error message	Possible cause	Remedial action
		mode is set to zero.	screen”.
E142 […] E145	**Error**		Refer to E004
E147	**Unknown instrument**	An Olympus HF instrument has not been properly connected to the UNIVERSAL socket.	Check the connection of the Olympus HF instrument to the UNIVERSAL socket.
		The instrument connected to the Multifunction socket can not be determined.	Change the connected instrument at the Multifunction socket
E148	**Unknown instrument**	An Olympus HF instrument has not been properly connected to the UNIVERSAL socket.	Check the connection of the Olympus HF instrument to the UNIVERSAL socket.
		A short circuit at the Multifunction socket has been detected.	Change the connected instrument at the Multifunction socket Send back to Olympus Service
E149	**Unknown instrument**	An Olympus HF instrument has not been properly connected to the UNIVERSAL socket.	Check the connection of the Olympus HF instrument to the UNIVERSAL socket.
		A malfunction at the Multifunction socket has been detected.	Change the connected instrument at the Multifunction socket Send back to Olympus Service
E150	**Error**		Refer to E004
E151	**Unknown instrument**	An Olympus HF instrument has not been properly connected to the UNIVERSAL socket.	Check the connection of the Olympus HF instrument to the UNIVERSAL socket.
		Invalid power setting detected at the instrument connected to the Multifunction socket.	Change the Instrument at the Multifunction socket
E152	**Unknown instrument**	An Olympus HF instrument has not been properly connected to the UNIVERSAL socket.	Check the connection of the Olympus HF instrument to the UNIVERSAL socket.
		Invalid effect setting detected at the instrument connected to the Multifunction socket.	Change the Instrument at the Multifunction socket

Error no.	Error message	Possible cause	Remedial action
E153	**Unknown instrument**	An Olympus HF instrument has not been properly connected to the UNIVERSAL socket.	Check the connection of the Olympus HF instrument to the UNIVERSAL socket.
		Invalid default Cut Mode detected at the instrument connected to the Multifunction socket.	Change the Instrument at the Multifunction socket
E154	**Unknown instrument**	An Olympus HF instrument has not been properly connected to the UNIVERSAL socket.	Check the connection of the Olympus HF instrument to the UNIVERSAL socket.
		Invalid default Coag Mode detected at the instrument connected to the Multifunction socket.	Change the Instrument at the Multifunction socket
E159	**Unknown instrument**	An Olympus HF instrument has not been properly connected to the UNIVERSAL socket.	Check the connection of the Olympus HF instrument to the UNIVERSAL socket.
		Invalid Mode detected at the instrument connected to the Multifunction socket.	Change the Instrument at the Multifunction socket
E165	**Error**		Refer to E004
E166	**Unknown instrument**	An Olympus HF instrument has not been properly connected to the UNIVERSAL socket.	Check the connection of the Olympus HF instrument to the UNIVERSAL socket.
		Invalid Version Number detected at the instrument connected to the Multifunction socket.	Change the Instrument at the Multifunction socket
E167	**Unknown instrument**	An Olympus HF instrument has not been properly connected to the UNIVERSAL socket.	Check the connection of the Olympus HF instrument to the UNIVERSAL socket.
		Internal software error.	Send back to Olympus Service
E168 E169 E170	**Error**		Refer to E004
E171 […] E178	**Error**	Internal hardware error.	Send back to Olympus Service
E179	**Temperature below limit**	The generator (Generator Board) is too cold.	Switch off the electrosurgical generator and wait until it has reached the specified operating temperature.
E180	**Temperature above limit**	The generator (Generator Board) is too hot.	Switch off the electrosurgical generator and wait until it has cooled down or reached the specified operating

Error no.	Error message	Possible cause	Remedial action
			temperature.
E181	**Temperature below limit**	The generator (HVPS Board) is too cold.	Switch off the electrosurgical generator and wait until it has reached the specified operating temperature.
E182	**Temperature above limit**	The generator (HVPS Board) is too hot.	Switch off the electrosurgical generator and wait until it has cooled down or reached the specified operating temperature.
E183 E184 E185	**Error**		Refer to E132
E186	**Error**	Internal hardware error.	Send back to Olympus Service
E187	**Increased HF leakage current**	The high frequency leakage current has exceeded the limit of 150 mA for monopolar application or 100 mA for bipolar application.	Check if an instrument, the neutral electrode or the patient is unintentionally grounded.
E188	**Excessive HF leakage current**	The high frequency leakage current has exceeded the limit of 300 mA for monopolar application or 200 mA for bipolar application.	Check if an instrument, the neutral electrode or the patient is unintentionally grounded.
E189 […] E198	**Error**		Refer to 132
E199	**Error**		Refer to 133
E200 E201	**Error**		Refer to 132
E202	**Insufficient neutral electrode contact**	The contact resistance of the neutral electrode is too high or the neutral electrode is not connected.	Check the connection / attachment of the neutral electrode.
		Malfunction of the neutral electrode and / or the neutral electrode cable.	Replace the neutral electrode and / or the cable.
E203 […] E213	**Error**		Refer to E020
E214	**Low battery**	The batteries on the Motherboard are low and caused a loss of data.	Replace the batteries on the Motherboard
E215	**Error**		Refer to E020
E216 E217	**Error**		Refer to E058
E218	**Error**		Refer to E020
E220	**Error**	Internal software or hardware error.	Send back to Olympus Service
E222 […]	**Error**		Refer to E058

Error no.	Error message	Possible cause	Remedial action
E294			
E295	**Error**	Unable to read the data at the Multifunction socket.	1. Change the connected instrument at the Multifunction socket.
			2. Send back to Olympus Service
E296	**Error**	Unable to write the data from the Multifunction socket.	1. Change the connected instrument at the Multifunction socket.
			2. Send back to Olympus Service
E297	**Error**	Unable to read the instrument name from the Multifunction socket.	1. Change the connected instrument at the Multifunction socket.
			2. Send back to Olympus Service
E299 […] E387	**Error**		Refer to E058
E390	**Communication error**	Improper connection of the communication cables to the LINK-OUT / LINK-IN socket: “The communication to other devices has been aborted.”	1. Check all cable connections.
			2. Check all other connected devices.
			3. Send back to Olympus Service
		Malfunction or damage of the communication cables.	Check the cables for damages and, if necessary, replace the cables.
E391 E392 E393	**Error**		Refer to E058
E394	**Communication error**	Improper connection of the communication cables to the LINK-OUT / LINK-IN socket: “The ring connection to other devices has been detected.”	1. Check all cable connections.
			2. Check all other connected devices.
			3. Send back to Olympus Service
		Malfunction or damage of the communication cables.	Check the cables for damages and, if necessary, replace the cables.
E396	**Temperature below limit**	The generator (Generator Board) is too cold.	Place the generator at normal room temperature and wait until it is warmed up before use.
E397	**Temperature above limit**	The generator (Generator Board) is too hot.	Wait until the generator has cooled down.
E398	**Temperature below limit**	The generator (HVPS Board) is too cold.	Place the generator at normal room temperature and wait until it is warmed up before use.
E399	**Temperature above limit**	The generator (HVPS Board) is too hot.	Wait until the generator has cooled down.
E400 […] E408	**Error**		Refer to E058
E409	**Communication error**	Improper connection of the communication cables to the LINK-OUT / LINK-IN socket:	1. Check all cable connections.
			2. Check all other connected devices.

Error no.	Error message	Possible cause	Remedial action
		"The communication problem to other devices has been detected."	3. Send back to Olympus Service
		Malfunction or damage of the communication cables.	Check the cables for damages and, if necessary, replace the cables.
E410	**Error**		Refer to E058
E411	**Communication error**	Improper connection of the communication cables to the LINK-OUT / LINK-IN socket: "The communication problem to other devices has been detected."	1. Check all cable connections.
			2. Check all other connected devices.
			3. Send back to Olympus Service
		Malfunction or damage of the communication cables.	Check the cables for damages and, if necessary, replace the cables.
E412	**Error**		Refer to E058
E413	**Error**	The controlled output power at the Burn-In is below the limit.	Check the connected resistors.
E414	**Error**	The controlled output power at the Burn-In is above the limit.	Send back to Olympus Service
415 […] 429	**Error**		Refer to E004
E430	**---**	--- (POWER_FAIL)	---
E431	**Error**		Refer to E004
E432 E433	**Error**		Refer to E133
E434 […] E437	**Error**		Refer to E004
E438	**Procedure data error**	One or more saved procedures have been deleted. (Inconsistant Procedure data detected. One or more Procedure settings have been lost.)	Press the "OK button" to close the error window and to continue.
E439 E440	**Error**	Internal hardware error.	Send back to Olympus Service
E441	**Device setting error**	All settings of the electrosurgical generator have been set to default. (SRAM and EEPROM content has been initialized.)	The electrosurgical generator is ready to use after the error window disappeared.
E443 […] E456	**Error**		Refer to E004
E457	**Error**	Internal software or hardware error.	Send back to Olympus Service
E458	**Error**		Refer to E058

Error no.	Error message	Possible cause	Remedial action
E459 E460	**Error**		Refer to E133
E461 […] E484	**Error**		Refer to E058
E486	**No instrument connected**	An Olympus HF instrument and / or connection cable has not been properly connected to the UNIVERSAL socket.	Ensure the proper connection of the Olympus HF instrument and / or the connection cable to the UNIVERSAL socket.
		Malfunction of the Olympus HF instrument and / or the connection cable.	Replace the Olympus HF instrument and / or the connection cable.
E488 E489	**Error**		Refer to E058
E490	**Communication error**	Improper connection of the communication cables to the LINK-OUT / LINK-IN socket: “The communication problem to other devices has been detected.”	1. Check all cable connections. 2. Check all other connected devices. 3. Send back to Olympus Service
		Malfunction or damage of the communication cables.	Check the cables for damages and, if necessary, replace the cables.
E491 […] E514	**Error**		Refer to E058
E515	**Communication error**	Improper connection of the communication cables to the LINK-OUT / LINK-IN socket: “The communication problem to other devices has been detected.”	1. Check all cable connections. 2. Check all other connected devices. 3. Send back to Olympus Service
		Malfunction or damage of the communication cables.	Check the cables for damages and, if necessary, replace the cables.
E516	**Communication error**	Improper connection of the communication cables to the LINK-OUT / LINK-IN socket: “The communication problem to other devices has been detected.”	1. Check all cable connections. 2. Check all other connected devices. 3. Send back to Olympus Service
		Malfunction or damage of the communication cables.	Check the cables for damages and, if necessary, replace the cables.
E519 […] E524	**Error**		Refer to E058
E525	**Error**		Refer to E020

Error no.	Error message	Possible cause	Remedial action
E526			
E527 […] E611	**Error**		Refer to E058

CHAPTER 5: INSPECTION

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1 Jigs, Tools, and Measuring Equipment for Inspection

No.	Name	Model/REF	Specifications/Remarks
J001	**Electrical safety tester**		e.g.: Seculife ST, Unimet 1000 ST (Bender), QA-90 (Metron)
J002	**Electrosurgical analyzer**		e.g.: QA-ES (Metron)
J003	**Digital multimeter**		DC accuracy: < 1 %, DC voltage range 500 V
J004	**Load resistors** **(low power)**		low inductive part, short time load 5 Ω, 140 Ω, 170 Ω all 0.5 W (or more) and 1 % tolerance or alternatively: resistor decade box
J005	**Load resistors** **(high power, low inductive)**		Low inductive part, 75 Ω, 500 Ω (300 W, 5%) 7 Ω, 916 Ω, 10 kΩ (100 W, 1%)
J007	**Cables, 4 mm to 4 mm (banana)**		Connection cable: monopolar or bipolar output (1 x 4 mm) to various equipment (1 x 4 mm, banana plug), length 1 m **WARNING**: A connection of a 4 mm plug to any other receptacle except the right-hand-side receptacle of the MONOPOLAR 1 socket and the MONOPOLAR 2 socket may destroy the socket during activation.
J008	**Cable, UNIVERSAL to 4 mm (banana)**	WB979008	Connection cable: bipolar UNIVERSAL to various equipment (1 x 4 mm, banana plug), length 1 m
J009	**Cable, Monopolar 1 including handswitch**	WB979013	Connection Cable: monopolar output incl. handswitch to various equipment (1 x 4 mm, banana plug), length 3…4 m
J010	**Cable, Monopolar 2 including handswitch**	WB979014	Connection Cable: monopolar output incl. handswitch to various equipment (1 x 4 mm, banana plug), length 3…4
J011	**Cable, neutral electrode (P-cord) to 2 x 4 mm (banana)**	WB979002	Connection cable: neutral electrode output (2 x 2.5 mm, 10 mm, P-cord) to various equipment (2 x 4 mm, banana plug), length 1 m
J012	**Cable, Communication**	MAJ-1871	Communication cable, length 0.25 m
J013	**Crocodile clips (with 4 mm connection)**		For connection to Potential Equalization bonding
J014	**ESG-400 foot switch double pedal**	WB50402W	
J015	**ESG-400 foot switch single pedal**	WB50403W	
J016	**Power Cord**		Ordering depending on country. Refer to Chapter 1-4-2
J017	**Oscilloscope**		e.g.: DSOX2024A (Agilent)
J018	**High Voltage Probe**		Attenuation: 100:1 Max. Input Voltage ≥ 850 Vp

2 Inspection procedures

The electrosurgical generator and the footswitch must undergo an inspection / safety check in yearly intervals in accordance with the national statutory regulations. Inspection is also mandatory after repair, adjustment, update and upgrade.

Generally the footswitches are inspected together with the electrosurgical unit. If a footswitch alone has to be checked, only following tests are mandatory. The Numbers used referring to the Inspection Card in chapter 5-3:

For a single footswitch test number 2, 39 and 55 are mandatory.

For a double footswitch test number 2, 38, 39 and 55 are mandatory.

Follow these test instructions. All tests must be done with fully functional and calibrated test equipment and by technicians trained in the service / maintenance of electrical medical devices. Record the test results in the “Inspection Card” (refer to chapter 5-3, Inspection Card) for reference in future tests and provide the user of the electrosurgical unit with a signed report.

During service / maintenance take care of the different hardware and software versions which may be applicable. Information how to identify the hardware version can be found in chapter 3-2, Board Compatibility. Information how to identify the software version can be found in chapter 1-3, Software version.

If the electrosurgical unit fails to meet any of the checks, the unit has to be adjusted according to chapter 6 (Adjustment) or refer to chapter 4 (Troubleshooting). If the failure still occurs, contact the manufacturer.

CAUTION To avoid inadvertent coupling and / or shunting of high frequency currents around the resistor elements, keep the resistors at least 10 centimeters away from any metal surface including tabletops and other resistors. This is especially true if several resistors are connected in series or parallel to obtain a specified value. Do not allow the resistor bodies to touch each other.

NOTE Keep test leads to the minimum length usable; lead inductance and stray capacitance can adversely affect readings.

Carefully select suitable ground points to avoid ground loop error in measurements.

For tests and checks requiring a power cord, use the power cord provided with the electrosurgical unit.

Inspection is mandatory after repair, adjustment, update and upgrade.

2-1 Visual inspection of the electrosurgical generator and accessories

1) Check that the labels according to chapter 5-1 (Front panel, Rear panel) are present and legible. The product name should be clearly visible on the front panel. Verify that the *type plate* shows details about the type of the device, reference number, line voltage range, supply frequency, output power classification, output frequency, duty cycle, serial number, manufacturing date and manufacturer according to Fig. 5.2.1, Fig. 5.2.2 or Fig. 5.2.3

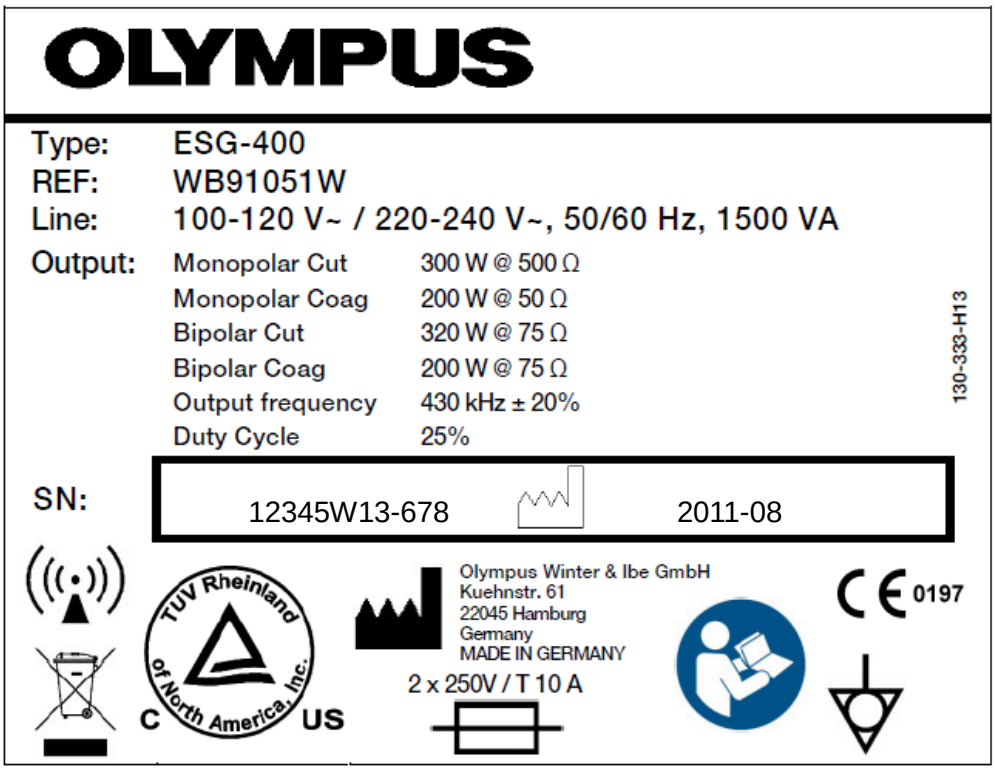

OLYMPUS
Type: ESG-400
REF: WB91051W
Line: 100-120 V~ / 220-240 V~, 50/60 Hz, 1500 VA
Output: Monopolar Cut 300 W @ 500 Ω
Monopolar Coag 200 W @ 50 Ω
Bipolar Cut 320 W @ 75 Ω
Bipolar Coag 200 W @ 75 Ω
Output frequency 430 kHz ± 20%
Duty Cycle 25%
130-333-H13
SN: 12345W13-678 2011-08
Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany
MADE IN GERMANY
2 x 250V / T 10 A
CE 0197
TUV Rheinland of North America, Inc.
C US

Fig. 5.2.1. Sample of type plate of the electrosurgical unit

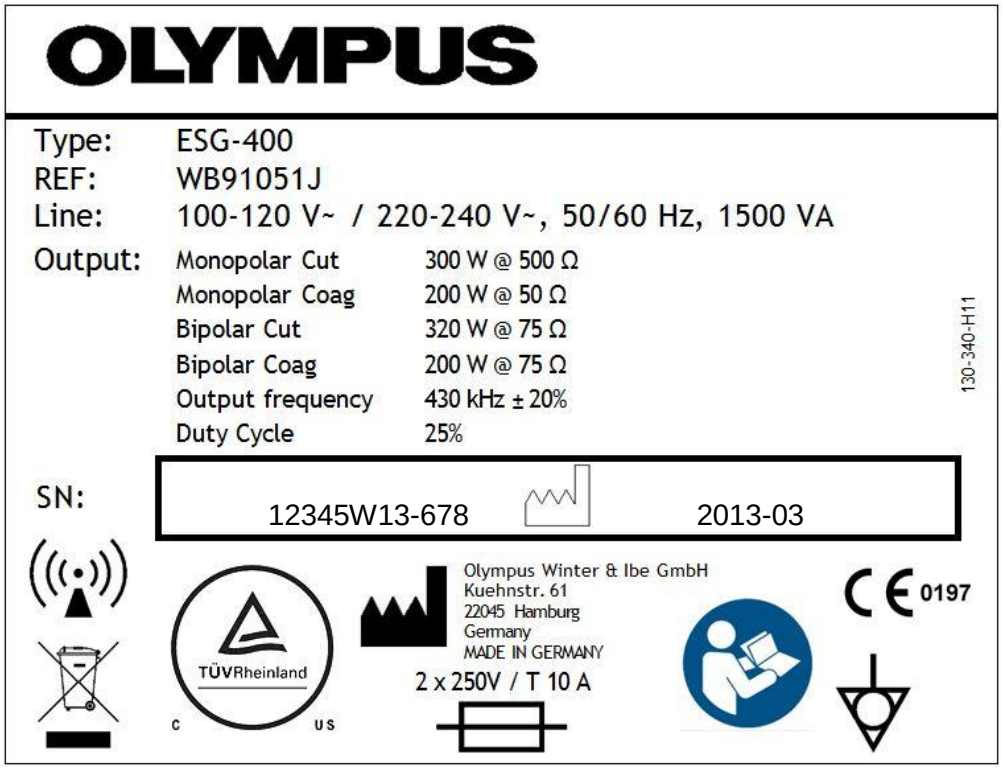


Fig. 5.2.2 Sample of type plate of the electrosurgical unit (Japan Version)

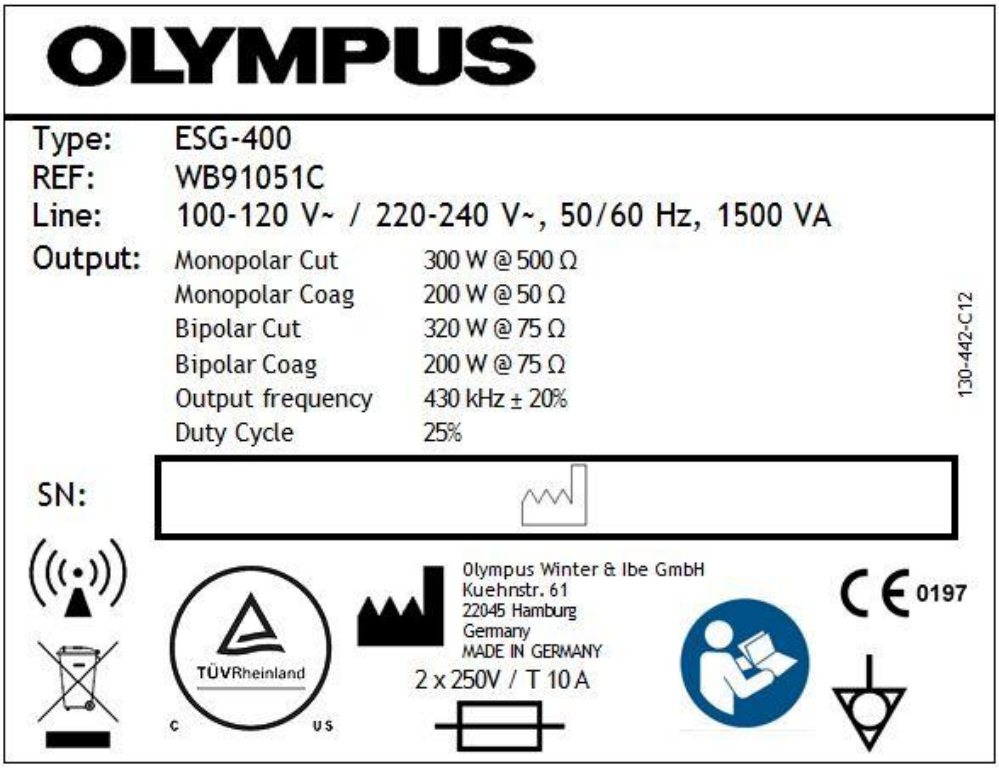


Fig. 5.2.3 Sample of type plate of the electrosurgical unit (China Version)

2) Check the electrosurgical unit and the accessories for external obstructions or damage. Verify that the housing, the front panel and the rear panel have no serious destructions.

3) Record the test results in the safety check report (refer to chapter 5-3).

4) Copy the tables 7.1 and 7.2 on the next page and prepare them to be filled out while inspecting the electrosurgical generator. Fill out the table 7.1 after the first startup of the generator. The field “Actual Procedure” can only be filled, if a procedure is chosen.

5) The table 7.2 is used every time before a mode is changed in order to perform a test. The settings of the used mode are noted in one line of table 7.2. Restore the values of table 7.2 either after each performed test or after the inspection. This should be done, to make sure that the physician will be provided with the last output power setting.

Actual Procedure	<if applicable>			
Actual Screen	**BIPOLAR**		**MONOPOLAR 1**	
	Cut Mode	Coag Mode	Cut Mode	Coag Mode
	UNIVERSAL		**MONOPOLAR 2**	
	Cut Mode	Coag Mode	Cut Mode	Coag Mode

Table 7.1: Template to note the actual procedure and the user assignment of the modes to the sockets

Socket	**Mode**	**Power Level**	**Effect**

Table 7.2: Template to note the power settings

2-2 Verifying the contact quality monitor function

1) Connect the *power cord* and the *footswitch* to the electrosurgical generator (refer to chapter 1-5-3 and 1-5-8).

2) All steps for this test are described in the table 7.3 at the next page. Assign the footswitch according to the column “Mode”. Connect the appropriate resistor R (J004) described in the column “Action” via the *connection cable* (J011) with the *neutral electrode socket* at the front panel (refer to chapter 1-5-2). For some tests leave the connector open or short circuit the *connection cable* (J011).

3) Follow the steps described in the column “Action” and verify the reaction of the corresponding *contact quality monitor indicator for non-split neutral electrode or split neutral electrode* at the front panel (refer to chapter 1-5-2) according to table 7.3.

4) Repeat step 2 and 3 until all action items in table 7.3 have been checked.

5) Record the test results in the Inspection Card (refer to chapter 5-3).

NOTE Always disconnect the *neutral electrode connector (J011)* before connecting a new resistor.

Mode	Action	Expected test result
Any bipolar mode	**During standby and activation** 1) The neutral electrode socket is left open, nothing is connected. 2) Activate any bipolar output.	 The *contact quality monitor* is independent from the bipolar mode. The indicator for *split neutral electrode* is illuminated red. During activation the HF-output is working.
Any monopolar mode	**During standby:** 1) Short circuit the neutral electrode connector. 2) Connect a R = 5 Ω with the *neutral electrode socket*	 *Pop-Up Window* at the screen will appear: “Non-split neutral electrode is connected” *Contact quality monitor indicator for non-split neutral electrode* illuminates green.
	During standby: 1) Connect a R = 140 Ω with the neutral electrode connector	 *Contact quality monitor indicator for split neutral electrode* illuminates green.
	During standby and activation: 1) Connect a R = 170 Ω, with the *neutral electrode connector* 2) Activate any monopolar output.	 *Contact quality monitor indicator for split neutral electrode* illuminates red. During activation a warning tone can be heard, the error code E202 is displayed (“Insufficient neutral electrode contact”) and **activation is disabled.**

Table 7.3: Checking the contact quality monitor

2-3 Checking the DC resistance (according to IEC 60601-2-2)

1) Activate the safety test function in the service menu (see chapter 6-1, Safety Test) and verify that the button “Relays on” is marked white.

2) Connect the digital multimeter (J003) with the *bipolar connector* on the front panel (see chapter 1-5-2).

3) Verify the resistance is ≥ 2 MΩ.

4) Deactivate the safety test function in the service menu.

5) Record the test results in the Inspection Card (see chapter 5-3).

2-4 Checking the earth resistance (according to IEC 60601-1 and IEC 62353)

1) Connect the electrosurgical generator with an electrical safety tester (J001) according to the tester’s instructions for use.

2) If the power cord and the electrosurgical unit are measured together, verify the protective earth resistance ≤ 0.3 Ω against metal parts which can be touched.

3) Record the test results in the Inspection Card (see chapter 5-3).

2-5 Checking the earth leakage current (according to IEC 60601-1)

1) Connect the electrosurgical generator with an electrical safety tester (J001) according to the tester’s instructions for use.

2) Switch on the electrosurgical unit.

3) Verify under normal condition (NC) the earth leakage current is ≤ 0.5 mA.

4) Verify under single fault condition (SFC) the earth leakage current is ≤ 1.0 mA

5) Record the test results in the Inspection Card (see chapter 5-3).

2-6 Checking the patient leakage current (according to IEC 60601-1)

NOTE For this test an interconnection of the three receptacles of MONOPOLAR 1 and MONOPOLAR 2 is allowed. Before interconnect the three receptacles verify, that the safety test function is activated and the button “Relays on” is marked white.

1) Switch the electrosurgical generator on and activate the safety test function in the service menu (see chapter 8-2, Safety Test) and verify that the button “Relays on” is marked white.

2) Connect the UNIVERSAL cable (J008) to the UNIVERSAL socket and the connection cable P-cord (J011) to the neutral socket.

3) Connect two 4mm cables “banana” (J007) to every receptacle of the BIPOLAR socket.

4) Connect three 4mm cables “banana” to the 4mm receptacles of the MONOPOLAR 1 socket. Leave the 8 mm BOVIE connector open.

5) Connect three 4mm cables “banana” to the 4mm receptacles of the MONOPOLAR 2 socket. Leave the 5/9 mm ERBE connector open.

6) Verify again that the Button “Relays on” at the touch screen is marked white and short circuit all connectors.

7) Switch the electrosurgical generator off, cable it with the electrical safety tester (J001) according to the tester’s instructions for use and switch it on again. Start the test with the electrical safety tester according to the tester’s instructions for use.

8) Verify under normal condition (NC) for AC the patient leakage current is ≤ 0.01 mA.

9) Verify under normal condition (NC) for DC the patient leakage current is ≤ 0.01 mA.

10) Verify under single fault condition (SFC, “open earth”) for AC the patient leakage current is ≤ 0.05 mA.

11) Verify under single fault condition (SFC, “open earth”) for DC the patient leakage current is ≤ 0.05 mA.

12) Disconnect all cables from the electrosurgical generator.

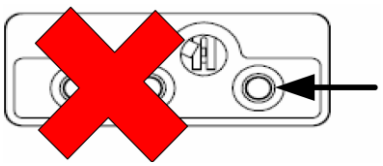
13) Deactivate the safety test function in the service menu.

14) Record the test results in the Inspection Card (see chapter 5-3).

2-7 Checking the current and power consumption and output waveform

CAUTION

A connection of a 4 mm plug to any other receptacle except the right-hand-side receptacle of the MONOPOLAR 1 socket and the MONOPOLAR 2 socket may destroy the socket during activation.



1) Connect the load resistor R_L = 500 Ω (J005) via a 4mm cable “banana” (J007) to the right receptacle of the *MONOPOLAR 1 socket* and via the connection cable “P-cord” (J011) to the *neutral socket* in the front panel.

2) Cable the electrosurgical generator with the electrical safety tester according to the testers instructions for use. Activate the function to measure current and power consumption.

3) Switch the electrosurgical generator on and select the PureCut (Effect 3) mode at the *MONOPOLAR 1 socket*. Set the level to 300. Assign the *footswitch* to the *MONOPOLAR 1 socket*. (Perform the setting according to the instruction for use.)

4) Activate the output power by pressing “CUT” at the footswitch.

5) Verify the current consumption I_L is ≤ 10 A.

6) Connect high voltage probe to oscilloscope and to generator output socket (signal to right receptacle of the *MONOPOLAR 1 socket* and signal ground to *neutral socket*)

   - Recommended oscilloscope settings:
     - Channel 1: high voltage probe 1000:1, DC, 200 V/div (minimum total voltage range displayed on oscilloscope: -700 V … +700 V)
     - Time:
       - minimum 2 ms/div (minimum total time range displayed on oscilloscope: 20 ms)
       - maximum 5 ms/div (maximum total time range displayed on oscilloscope: 50 ms)

7) Activate the output power by pressing “CUT” at the footswitch. Record the waveform in the time range after the high power cut support pulse (ca. 100 ms after HF output start) in steady state.

8) Verify output waveform:
   The amplitude level of the output voltage must be stable. No oscillation in the frequency range of 50 … 200 Hz. A maximum amplitude fluctuation from minimum peak voltage to maximum peak voltage of 110 V is allowed for steady state.

NOTE

Table 7.4 is showing good and bad examples how the output waveform should look like. From the figures in this table it is also clear to see, which parameter is to be measured.

9) Disconnect high voltage probe.

10) Connect the load resistor R_L = 75 Ω (J005) via the connection cable (J008) with the *UNIVERSAL socket* in the front panel.

11) Select the SalineCut (Effect 3) mode at the *UNIVERSAL socket*. Set the level to 320. Assign the *footswitch* to the *UNIVERSAL socket*. (Perform the setting according to the instruction for use.)

12) Activate the output power by pressing “CUT” at the footswitch.

13) Verify the apparent power consumption S_L is ≤ 1500 VA.

14) Record the test results in the Inspection Card (see chapter 7-3)

15) Switch the electrosurgical generator off and disassemble the test set-up.

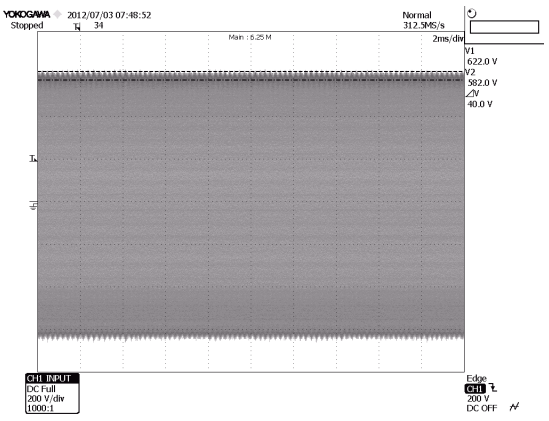
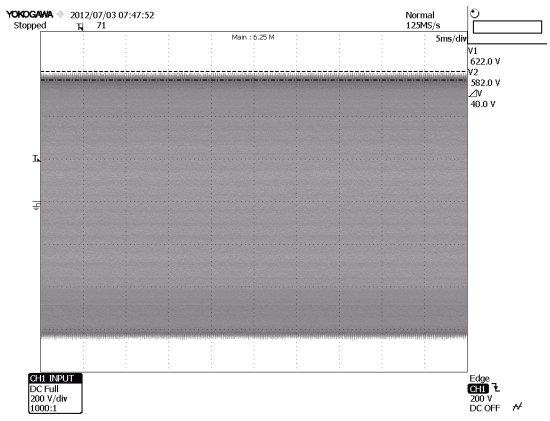
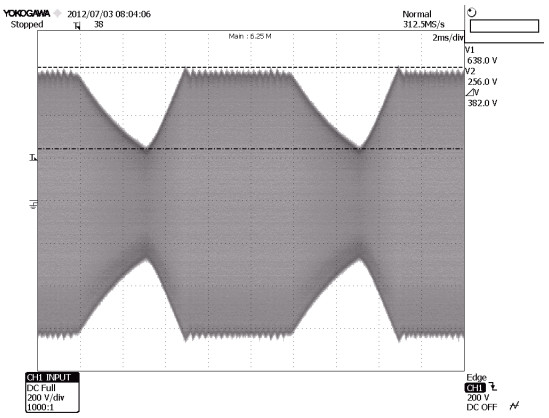
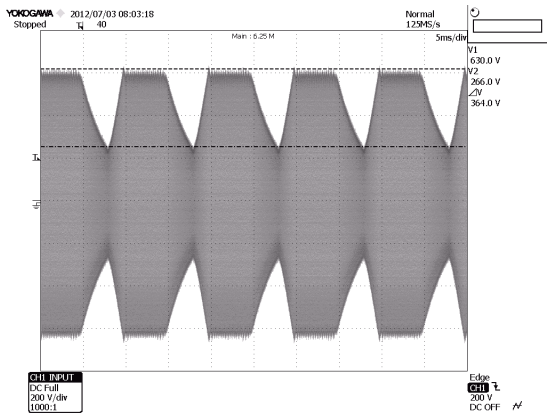
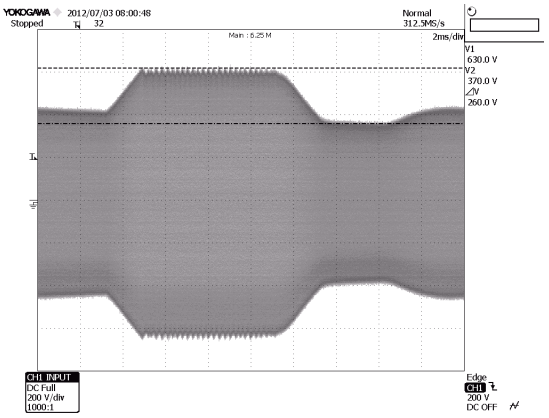
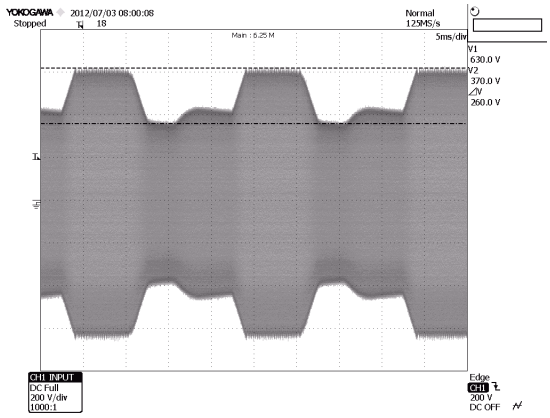
Setup	Picture of oscilloscope (2 ms / div)	Picture of oscilloscope (5 ms / div)
“good” example for WB91051W		
“bad” example for WB91051W with mains voltage of 230 VAC		
“bad” example for WB91051W with mains voltage of 115 VAC		

Table 7.4: good and bad examples of the output waveform

2-8 Checking the high frequency leakage current (according to IEC 60601-2-2)

The monopolar high frequency leakage current has to be measured according to the procedure 19.3.101 a) 2) (neutral electrode isolated from earth at high frequency) as described in IEC 60601-2-2.

The bipolar high frequency leakage current has to be measured according to the procedure 19.3.101 a) 3) (bipolar application) as described in IEC 60601-2-2.

The high frequency current is measured from the appropriate output connector of each pole while the electrosurgical unit is operated at maximum output power setting in an appropriate mode and the output being unloaded and loaded at rated load. The high frequency current is measured with the electrosurgical analyzer through an internal resistance of 200 Ω.

2-8-1 Measurement of the monopolar high frequency leakage current under loaded condition

CAUTION

A connection of a 4 mm plug to any other receptacle except the right-hand-side receptacle of the MONOPOLAR 1 socket and the MONOPOLAR 2 socket may destroy the socket during activation.

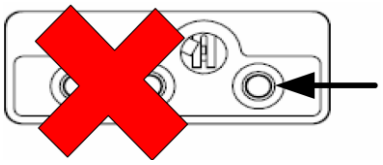


Fig. 5.2.4 and Fig. 5.2.5 are showing an example how to set up the test to measure the monopolar high frequency leakage current under loaded condition. The load resistor R_L = 500 Ω (J005) is connected via the connection cable (J007, banana) with the active pole MONOPOLAR 1 and via the connection cable J011 with the NEUTRAL connector. The high frequency leakage current is floating from appropriate pole to the equipotential bonding port. It is measured via the electrosurgical analyzer via a measuring resistance of 200 Ω. Fig. 5.2.4 shows the measurement from the neutral pole; Fig. 5.2.5 shows the measurement from the active pole.

1) Assign the footswitch to the *MONOPOLAR 1 socket* and select the monopolar PureCut mode with effect 3. Set the power level to 300. (Perform the setting according to the instruction for use.)

2) Set up the measurement according to Fig. 5.2.4 (Measuring of the high frequency leakage current under loaded condition at the neutral pole.)

3) Activate the output power by pressing the corresponding footswitch pedal.

4) Verify the leakage current is ≤ 150 mA.

5) Set up the measurement according to Fig. 5.2.5 (Measuring of the high frequency leakage current under loaded condition at the active pole.)

6) Activate the output power by pressing the corresponding footswitch pedal.

7) Verify the leakage current is ≤ 150 mA.

8) Repeat step 2 - 7 for the monopolar SprayCoag mode with effect 3 and power level 120.

9) Record the test results in the Inspection Card (see chapter 5-3).

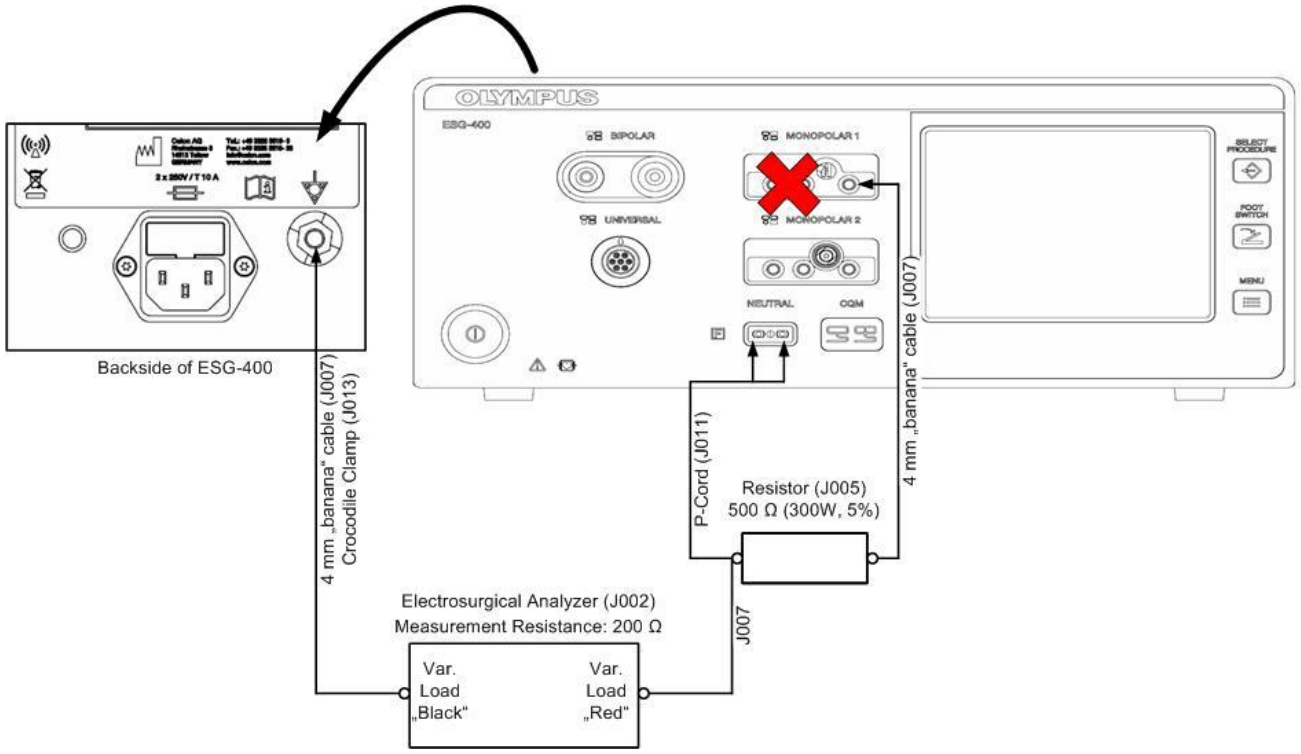


Fig. 5.2.4. Example for the loaded measurement of the monopolar high frequency leakage current at the neutral pole

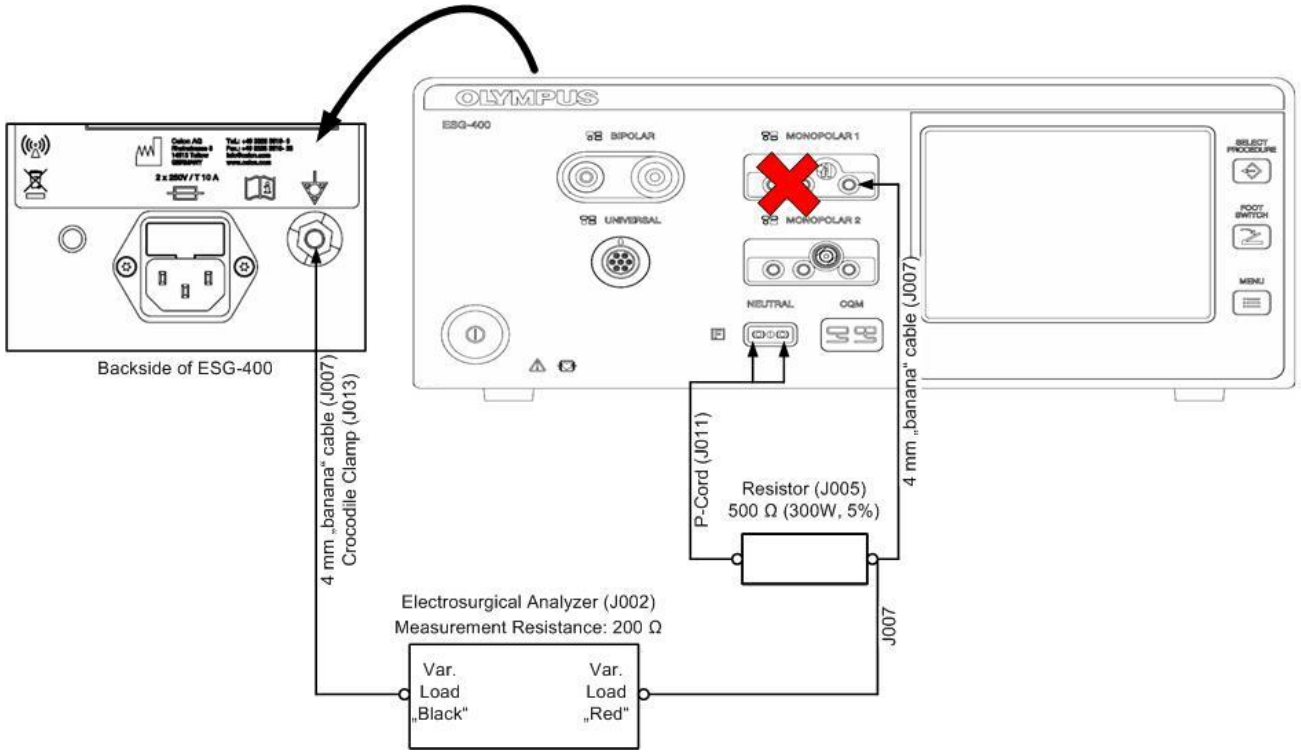


Fig. 5.2.5. Example for the loaded measurement of the monopolar high frequency leakage current at the active pole

CAUTION A connection of a 4 mm plug to any other receptacle except the right-hand-side receptacle of the MONOPOLAR 1 socket and the MONOPOLAR 2 socket may destroy the socket during activation.

2-8-2 Measurement of the monopolar high frequency leakage current under unloaded condition

CAUTION

A connection of a 4 mm plug to any other receptacle except the right-hand-side receptacle of the MONOPOLAR 1 socket and the MONOPOLAR 2 socket may destroy the socket during activation.

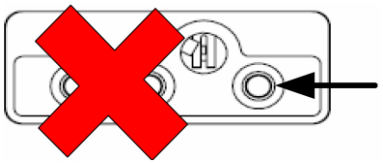


Fig. 5.2.6 and Fig. 5.2.7 are showing an example how to set up the test to measure the monopolar high frequency leakage current under unloaded condition. In this test the output is unloaded, the load resistance used in the test before is removed. The high frequency leakage current is floating from appropriate pole to the equipotential bonding port. It is measured via the electrosurgical analyzer via a measuring resistance of 200 Ω. Fig. 5.2.6 shows the measurement from the neutral pole; Fig. 5.2.7 shows the measurement from the active pole.

1) Assign the footswitch to the *MONOPOLAR 1 socket* and select the monopolar PureCut mode with effect 3. Set the power level to 300. (Perform the setting according to the instruction for use.)

2) Set up the measurement according to Fig. 5.2.6 (Measuring of the high frequency leakage current under unloaded condition at the neutral pole.)

3) Activate the output power by pressing the corresponding footswitch pedal.

4) Verify the leakage current is ≤ 150 mA.

5) Set up the measurement according to Fig. 5.2.7 (Measuring of the high frequency leakage current under unloaded condition at the active pole.)

6) Activate the output power by pressing the corresponding footswitch pedal.

7) Verify the leakage current is ≤ 150 mA.

8) Repeat step 2 - 7 for the monopolar SprayCoag mode with effect 3 and power level 120.

9) Record the test results in the Inspection Card (see chapter 5-3).

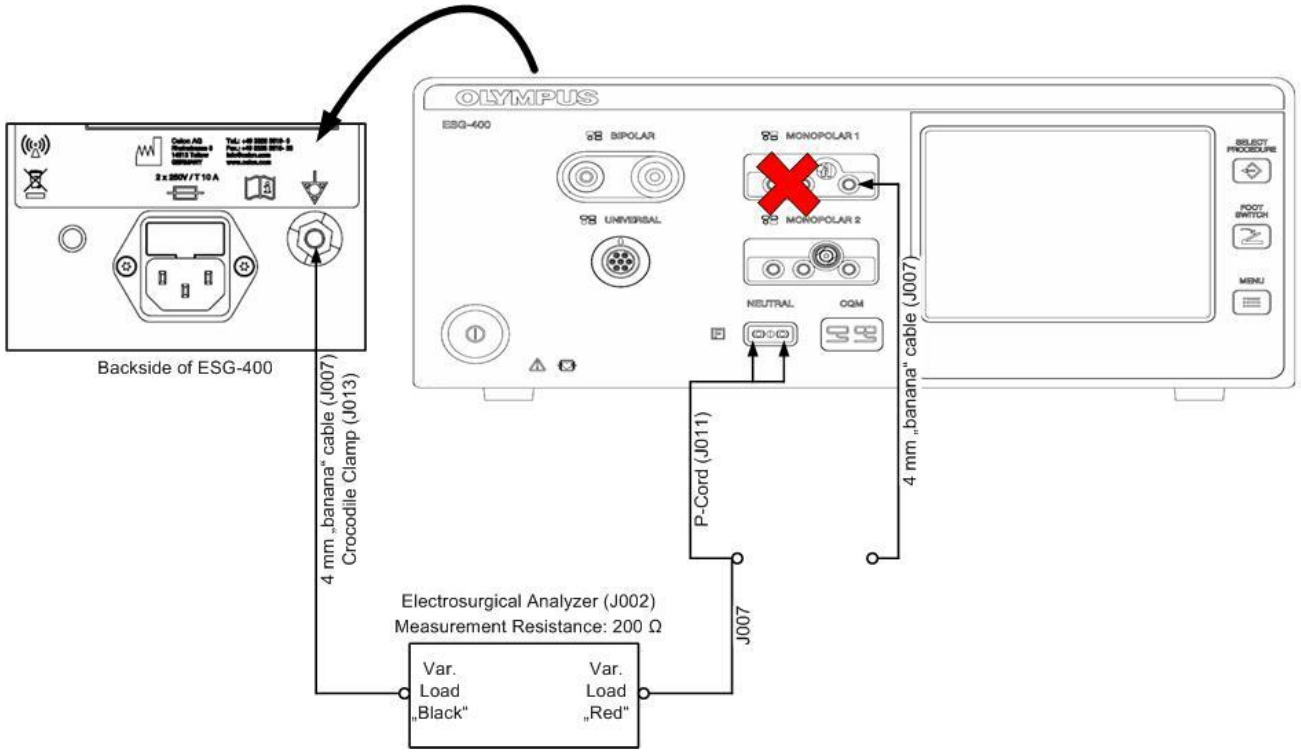


Fig. 5.2.6. Example for the unloaded measurement of the monopolar high frequency leakage current at the neutral pole

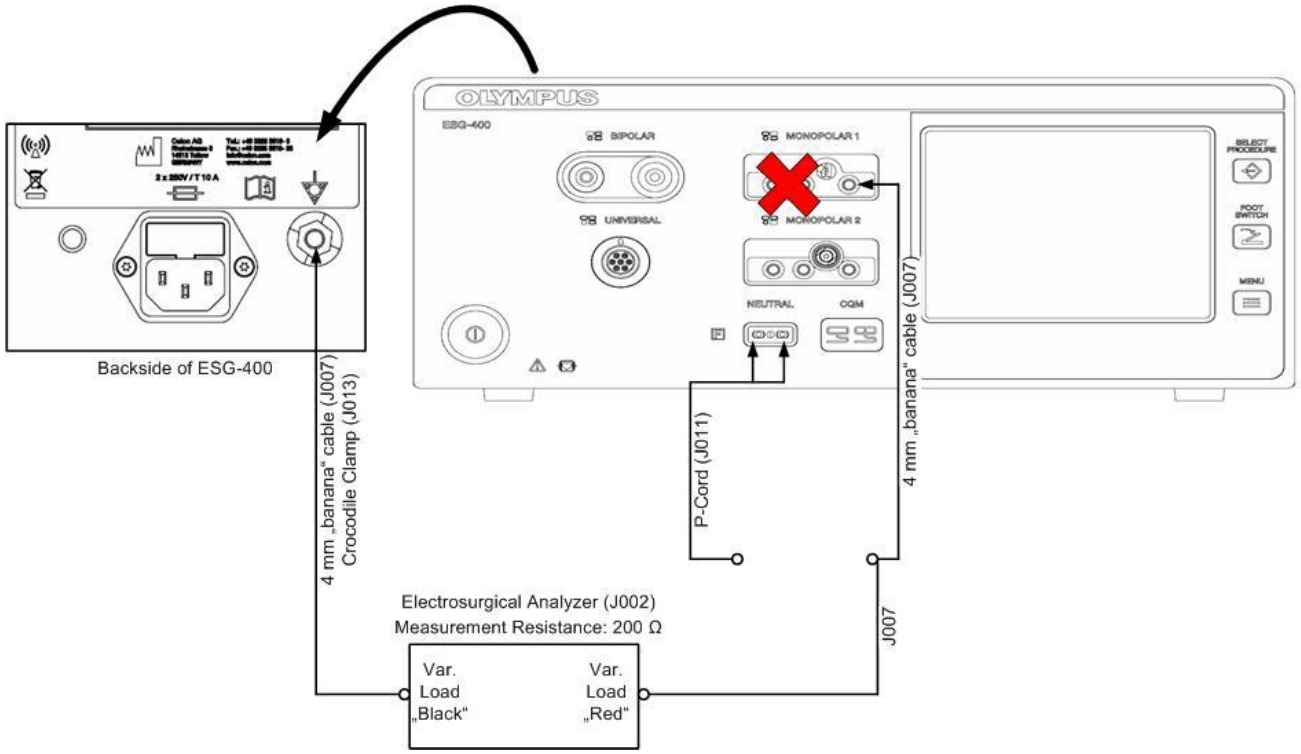


Fig. 5.2.7. Example for the unloaded measurement of the monopolar high frequency leakage current at the active pole

CAUTION A connection of a 4 mm plug to any other receptacle except the right-hand-side receptacle of the MONOPOLAR 1 socket and the MONOPOLAR 2 socket may destroy the socket during activation.

2-8-3 Measurement of the bipolar high frequency leakage current under loaded condition

CAUTION

A connection of a 4 mm plug to any other receptacle except the right-hand-side receptacle of the MONOPOLAR 1 socket and the MONOPOLAR 2 socket may destroy the socket during activation.

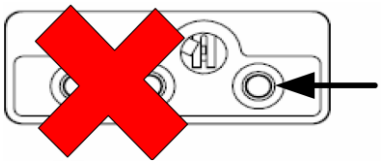


Fig. 5.2.8 and Fig. 5.2.9 are showing an example how to set up the test to measure the bipolar high frequency leakage current under loaded condition. The load resistor R_L = 500 Ω (J005) is connected via the connection cables (J007, banana) with both BIPOLAR receptacles. The high frequency leakage current is floating from appropriate pole to the equipotential bonding port. It is measured via the electrosurgical analyzer via a measuring resistance of 200 Ω. Fig. 5.2.8 shows the measurement from terminal 1; Fig. 5.2.9 shows the measurement from terminal 2.

1) Assign the footswitch to the BIPOLAR socket and select the BipolarCut mode with effect 3. Set the power level to 100. (Perform the setting according to the instruction for use.)

2) Set up the measurement according to Fig. 5.2.8 (Measuring of the high frequency leakage current under loaded condition at terminal 1.)

3) Activate the output power by pressing the corresponding footswitch pedal.

4) Verify the leakage current is ≤ 70 mA.

5) Set up the measurement according to Fig. 5.2.9 (Measuring of the high frequency leakage current under loaded condition at terminal 2.)

6) Activate the output power by pressing the corresponding footswitch pedal.

7) Verify the leakage current is ≤ 70 mA.

8) Record the test results in the Inspection Card (see chapter 5-3).

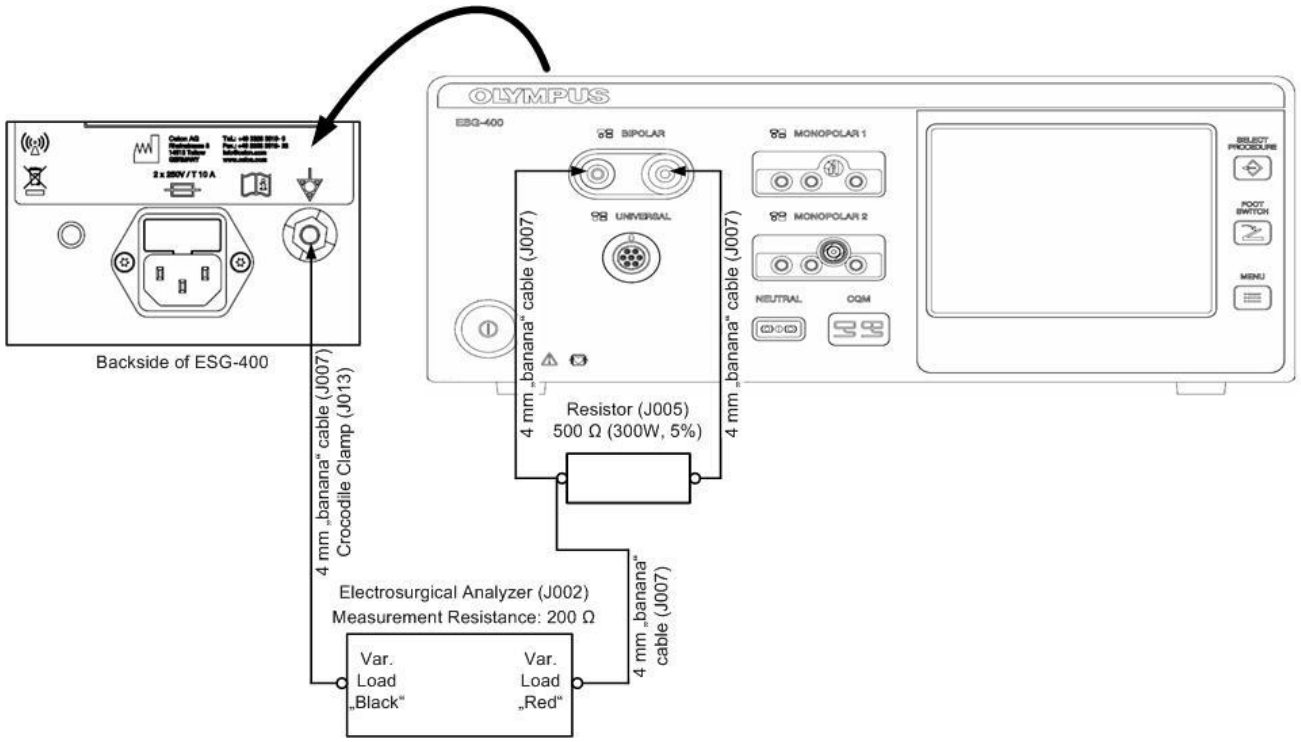


Fig. 5.2.8. Example for the loaded measurement of the bipolar high frequency leakage current at terminal 1

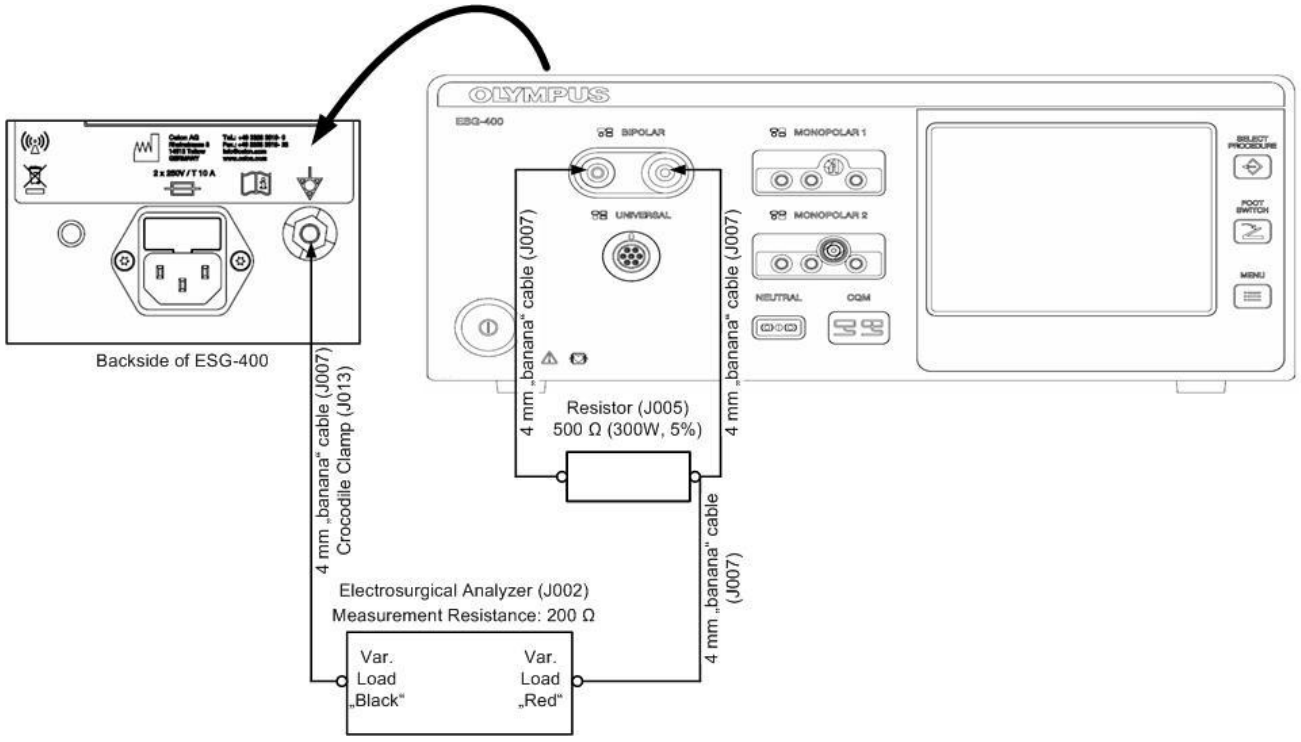


Fig. 5.2.9. Example for the loaded measurement of the bipolar high frequency leakage current at terminal 2

2-8-4 Measurement of the bipolar high frequency leakage current under unloaded condition

Fig. 5.2.10 and Fig. 5.2.11 are showing an example how to set up the test to measure the bipolar high frequency leakage current under unloaded condition. In this test the output is unloaded, the load resistance used in the test before is removed. The high frequency leakage current is floating from appropriate pole to the equipotential bonding port. It is measured via the electrosurgical analyzer via a measuring resistance of 200 Ω. Fig. 5.2.10 shows the measurement from terminal 1; Fig. 5.2.11 shows the measurement from terminal 2.

9) Assign the footswitch to the BIPOLAR socket and select the BipolarCut mode with effect 3. Set the power level to 100. (Perform the setting according to the instruction for use.)

10) Set up the measurement according to Fig. 5.2.10 (Measuring of the high frequency leakage current under unloaded condition at terminal 1.)

11) Activate the output power by pressing the corresponding footswitch pedal.

12) Verify the leakage current is ≤ 70 mA.

13) Set up the measurement according to Fig. 5.2.11 (Measuring of the high frequency leakage current under unloaded condition at terminal 2.)

14) Activate the output power by pressing the corresponding footswitch pedal.

15) Verify the leakage current is ≤ 70 mA.

16) Record the test results in the Inspection Card (see chapter 5-3).

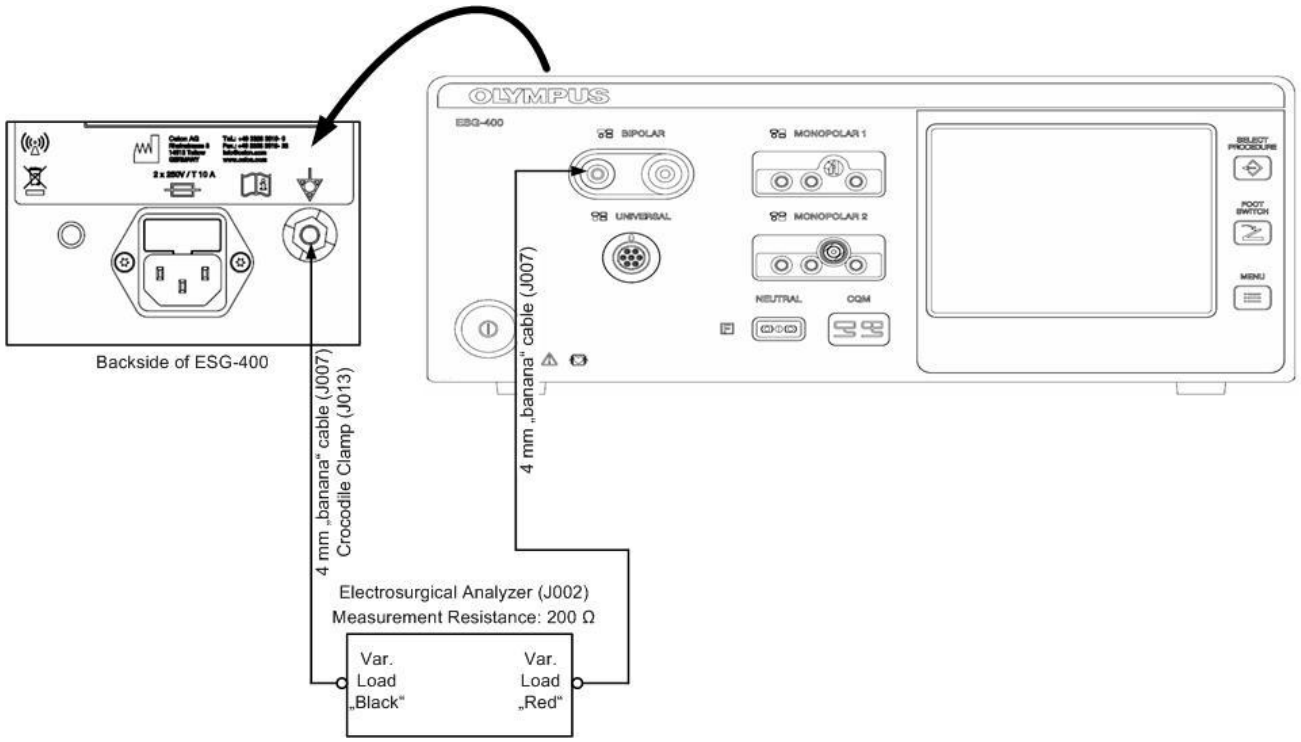


Fig. 5.2.10. Example for the unloaded measurement of the bipolar high frequency leakage current at terminal 1

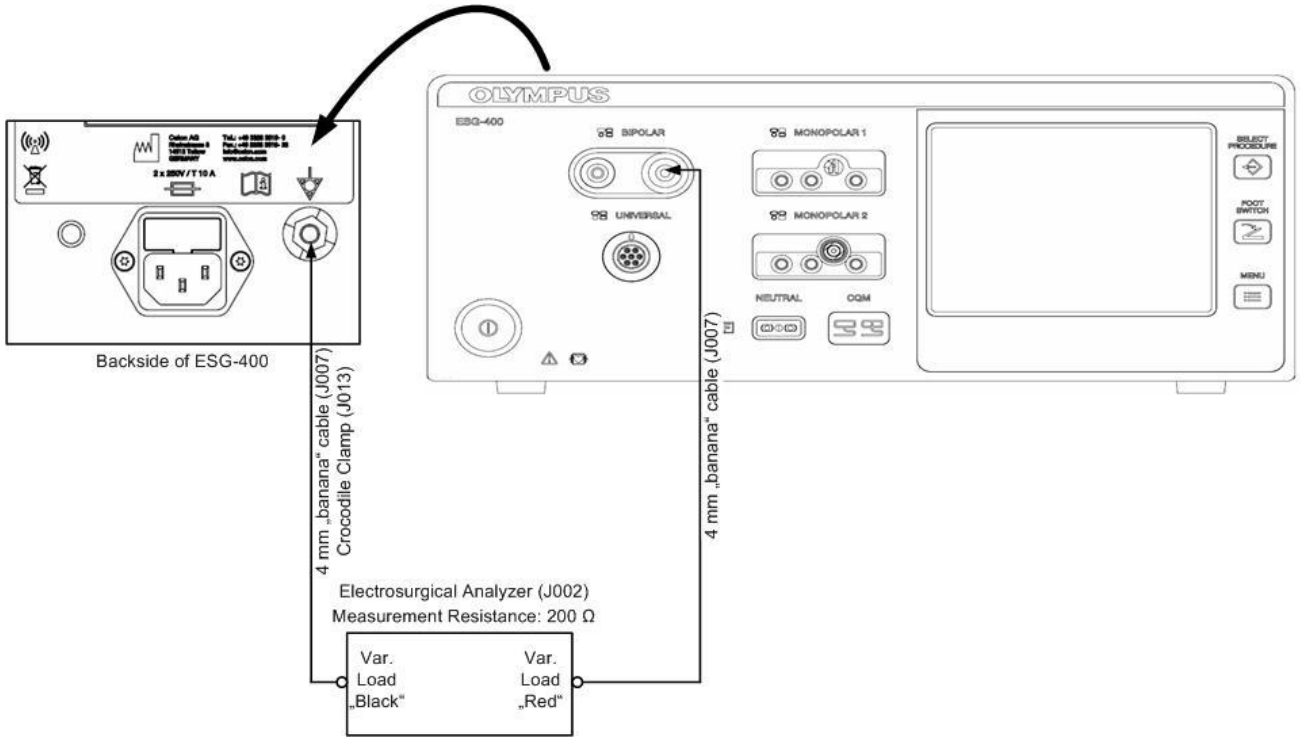


Fig. 5.2.11. Example for the unloaded measurement of the bipolar high frequency leakage current at terminal 2

2-9 Checking the output power

1) All constraints for these tests are listed in the inspection card in chapter 5-3 under number 30 to 45. The constraints are the output socket, the way of activation (e.g. footswitch, handswitch), the settings and the load resistance. For measuring and to simulate the appropriate resistance the electrosurgical analyzer (J002) is used.

2) Connect the appropriate output of the electrosurgical generator to the variable load of the electrosurgical analyzer (J002) (according to the inspection card in chapter 5-3). Set the electrosurgical generator to continuous measuring and set the internal measuring resistance to the appropriate value (according to the inspection card in chapter 5-3). Start the measuring with the electrosurgical generator. (Settings of the electrosurgical analyzer are done according to the analyzer's instruction for use.)

3) Select the mode and set the power level according to the inspection card in chapter 5-3.

4) Activate the output power by pressing the corresponding footswitch pedal or handswitch button. During the activated output the output tone can be heard.

5) Verify the output power is in the range according to the inspection card in chapter 5-3.

6) Repeat step 2 - 5 until test number 30 to 45 in the inspection card in chapter 5-3 have been checked.

7) Record the test results in the Inspection Card (see chapter 5-3).

NOTE For the measurement of this (high current) value, it is important, that the cable of the instrument is not "forming an inductor". So do not wrap it up like a coil. Either use it flat or unfold it completely.

2-10 Checking for certain features and error messages

1) All constraints for these tests are listed in the inspection card in chapter 5-3 under number 46 to 48. The constraints are the output socket, the way of activation (e.g. footswitch, handswitch), the settings and the load resistance. Low inductive high load resistors (J005) are used.

2) Connect the appropriate output of the electrosurgical generator to the appropriate load resistor (according to the inspection card in chapter 5-3).

3) Select the mode and set the power level according to the inspection card in chapter 5-3.

4) Activate the output power by pressing the corresponding footswitch pedal. During the activated output the output tone can be heard.

5) Verify the reaction of the electrosurgical generator according to the inspection card in chapter 5-3.

6) Repeat step 2 - 5 until test number 46 to 48 in the inspection card in chapter 5-3 have been checked.

7) Record the test results in the Inspection Card (see chapter 5-3).

2-11 Final test

2-11-1 Self test

1) Connect the electrosurgical generator via power cord (J016) to mains. Switch the generator on by pressing the “Power Switch”.

2) The generator should boot without any alarm. If an alarm occurs, refer to Chapter 4 (Troubleshooting).

2-11-2 Display and sound check

1) Check the adjustment of display brightness and volume via touch screen. Enter the “Select Menu” by pressing the push button “MENU push button”. Change the Volume via the rocker switch. A sound should be carried according to the setting. Change the Brightness via the rocker switch. The brightness should change according to the setting.

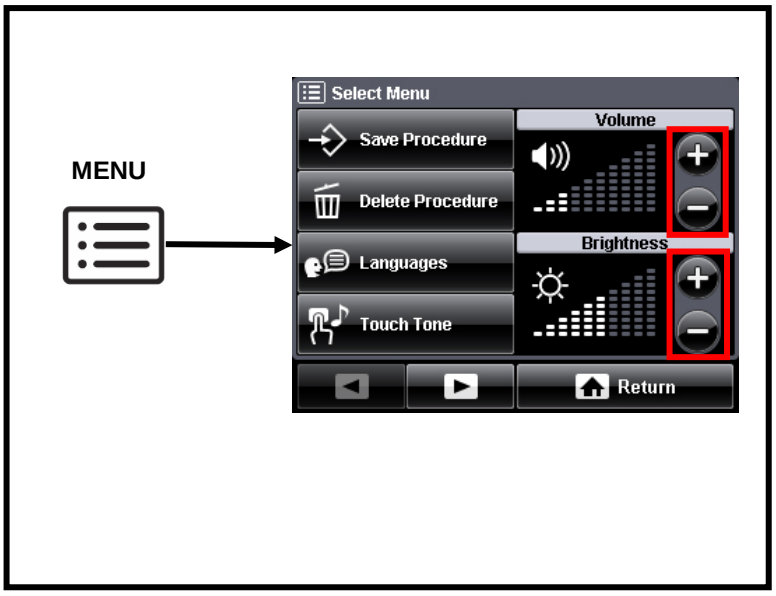


Fig. 5.2.12. Checking volume and brightness

2) Check the adjustment of the volume via the volume control knob at the rear of the housing.

   There will be an acoustic feedback for the setting.

3) Record the test results in the Inspection Card (refer to chapter 5-3).

2-11-3 Functionality of push buttons

1) Check the functionality of each push button by pressing.

2) The buttons should perform according to the description in the instruction for use.

3) Record the test results in the Inspection Card (refer to chapter 5-3).

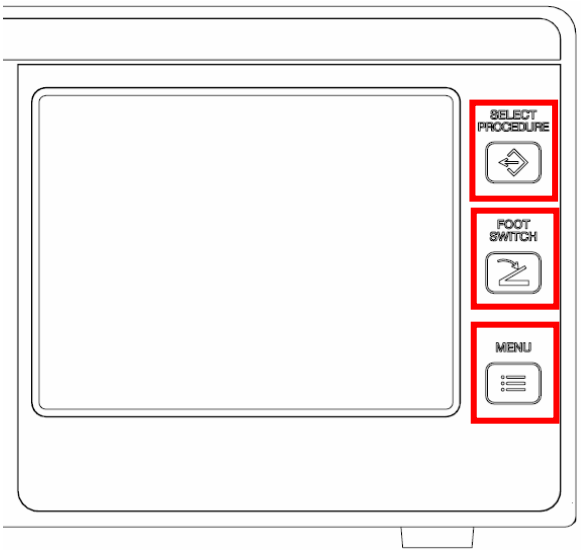


Fig. 5.2.13. Position of the push buttons

2-11-4 Communication test

1) Connect the sockets “LINK-IN” and “LINK-OUT” at the rear of the housing by the *Communication Cable*

(J012) with each other. In this way a ring communication is established.

2) The Error Message “E394 Communication error” should appear.

3) Record the test results in the Inspection Card (refer to chapter 5-3).

2-11-5 Restore of output power settings

Restore the settings by using the tables created in chapter 7-2-1. When not done while inspecting, restore all power settings off the changed modes noted in table 7.2. Finally restore the last active procedure if applicable and assign all modes to the sockets.

2-12 Inspection label (For applicable markets)

1) Cover or exchange an inspection label (as shown in Fig. 5.2.14) at the rear panel of the electrosurgical unit’s housing and mark the due date of the next periodic safety check (month / year). The electrosurgical unit must undergo a periodic safety check at annual intervals.

2) Record the due date in the safety check report (see chapter 5-3).

Fig. 5.2.14. Sample of an inspection label

3 Inspection Card

Product name:	
REF no.:	
Serial no.:	
Software version:	
Service / Maintenance manual version:	

Nr.	Test type / mode		Pwr. level Effect	Load resistance	Requirement	Measured value	Test passed	
							Yes	No
Visual inspection of the electrosurgical unit and accessories								
1	Labels		N/A	N/A	Procedure passed	N/A		
2	Obstructions or damage of unit and accessories		N/A	N/A	Procedure passed	N/A		
Contact quality monitor function								
3	Any bipolar mode		N/A	N/A	Procedure passed	N/A		
4	Any monopolar mode	Standby, non-split	N/A	0 Ω, 5 Ω	Procedure passed	N/A		
5		Standby, split	N/A	140 Ω	Procedure passed	N/A		
6		Standby, split	N/A	170 Ω	Procedure passed	N/A		
7		Activation, split	N/A	170 Ω	Procedure passed	N/A		
DC Resistance								
8	DC resistance		N/A	N/A	≥ 2.0 MΩ			
9	Earth resistance (with power cord)		N/A	N/A	≤ 0.3 Ω			
Earth leakage current								
10	Normal condition (NC)		N/A	N/A	≤ 0.5 mA			
11	Single fault condition (SFC)		N/A	N/A	≤ 1.0 mA			

Nr.	Test type / mode	Pwr. level Effect	Load resistance	Requirement	Measured value	Test passed Yes	 No
Patient leakage current							
12	Normal condition (NC), AC	N/A	N/A	≤ 0.01 mA			
13	Normal condition (NC), DC	N/A	N/A	≤ 0.01 mA			
14	Single fault condition (SFC), AC	N/A	N/A	≤ 0.05 mA			
15	Single fault condition (SFC), DC	N/A	N/A	≤ 0.05 mA			
Current and power consumption and output waveform							
16	PureCut	300 Eff. 3	500 Ω	I_L ≤ 10 A			
17	Amplitude fluctuation	300 Eff. 3	500 Ω	Δ ≤ 110 V			
18	SalineCut	320 Eff. 3	75 Ω	S_L ≤ 1500 VA			
High frequency leakage current							
19	Monopolar PureCut (neutral electrode terminal)	300 Eff. 3	500 Ω	≤ 150 mA			
20	Monopolar PureCut (active electrode terminal)	300 Eff. 3	500 Ω	≤ 150 mA			
21	Monopolar SprayCoag (neutral electrode terminal)	120 Eff. 3	500 Ω	≤ 150 mA			
22	Monopolar SprayCoag (active electrode terminal)	120 Eff. 3	500 Ω	≤ 150 mA			
23	Monopolar PureCut (neutral electrode terminal)	300 Eff. 3	unloaded	≤ 150 mA			
24	Monopolar PureCut (active electrode terminal)	300 Eff. 3	unloaded	≤ 150 mA			
25	Monopolar SprayCoag (neutral electrode terminal)	120 Eff. 3	unloaded	≤ 150 mA			
26	Monopolar SprayCoag (active electrode terminal)	120 Eff. 3	unloaded	≤ 150 mA			

Nr.	Test type / mode	Pwr. level Effect	Load resistance	Requirement	Measured value	Test passed Yes	 No
27	BipolarCut (active electrode terminal 1)	100 Eff. 3	500 Ω	≤ 70 mA			
28	BipolarCut (active electrode terminal 2)	100 Eff. 3	500 Ω	≤ 70 mA			
29	BipolarCut (active electrode terminal 1)	100 Eff. 3	unloaded	≤ 70 mA			
30	BipolarCut (active electrode terminal 2)	100 Eff. 3	unloaded	≤ 70 mA			
Output power							
31	Monopolar PureCut (hand switch@ MONOPOLAR 1)	300 Eff. 3	500 Ω	244 W ≤ P_{out} ≤ 366 W			
32	Monopolar SprayCoag (hand switch @ MONOPOLAR 1)	120 Eff. 3	500 Ω	93 W ≤ P_{out} ≤ 139 W			
33	Monopolar BlendCut (hand switch @ MONOPOLAR 2)	200 Eff. 3	500 Ω	154 W ≤ P_{out} ≤ 232 W			
34	Monopolar BlendCut (hand switch @ MONOPOLAR 2)	200 Eff. 3	2000 Ω	49 W ≤ P_{out} ≤ 73 W			
35	Monopolar PowerCoag (hand switch @ MONOPOLAR 2)	120 Eff. 3	500 Ω	93 W ≤ P_{out} ≤ 139 W			
36	Monopolar PowerCoag (hand switch @ MONOPOLAR 2)	60 Eff. 3	500 Ω	48 W ≤ P_{out} ≤ 72 W			
37	Monopolar SoftCoag (foot switch @ MONOPOLAR 2 with J007 without J010)	200 Eff. 3	50 Ω	154 W ≤ P_{out} ≤ 232 W			
38	Monopolar ForcedCoag (foot switch @ MONOPOLAR 2 with J007 without J010)	120 Eff. 3	500 Ω	93 W ≤ P_{out} ≤ 139 W			

Nr.	Test type / mode	Pwr. level Effect	Load resistance	Requirement	Measured value	Test passed Yes	 No
39	BipolarCut (**double** foot switch @ BIPOLAR)	100 Eff. 3	500 Ω	82 W ≤ P_{out} ≤ 122 W			
40	Bipolar AutoCoag (**single** foot switch (if provided with the generator, otherwise **double** footswitch) @ BIPOLAR)	120 Eff. 3	25 Ω	48 W ≤ P_{out} ≤ 72 W			
41	Bipolar AutoCoag (**double** foot switch @ BIPOLAR)	120 Eff. 3	75 Ω	94 W ≤ P_{out} ≤ 140 W			
42	Bipolar RFCoag (without RCAP) (foot switch @ BIPOLAR)	50 w/o RCAP	75 Ω	39 W ≤ P_{out} ≤ 59 W			
43	Bipolar RFCoag (without RCAP) (foot switch @ BIPOLAR)	50 w/o RCAP	1000 Ω	0 W ≤ P_{out} ≤ 5 W			
44	Bipolar FineCoag (foot switch @ BIPOLAR)	39 Eff. 1	50 Ω	35 W ≤ P_{out} ≤ 43 W			
45	Bipolar HardCoag (foot switch @ BIPOLAR)	42 Eff. 1	500 Ω	0 W ≤ P_{out} ≤ 12 W			
46	Bipolar SalineCoag (foot switch @ UNIVERSAL)	200 Eff. 3	75 Ω	154 W ≤ P_{out} ≤ 230 W Message “Use default instrument settings? (UNIVERSAL socket)” can be acknowledged.			

Nr.	Test type / mode	Pwr. level Effect	Load resistance	Requirement	Measured value	Test passed Yes	 No
Checking for certain error messages							
46	Bipolar FineCoag (foot switch @ BIPOLAR)	39 Eff. 1	7 Ω	Message “E002 Short circuit”	N/A		
47	Bipolar HardCoag (foot switch @ BIPOLAR)	42 Eff. 1	10 kΩ	Message “E001 Open circuit”	N/A		
48	Bipolar HardCoag (foot switch @ BIPOLAR)	42 Eff. 1	916 Ω	AEOP sound	N/A		
Final Check							
49	Self test	N/A	N/A	Procedure passed	N/A		
50	Display and sound check	N/A	N/A	Procedure passed	N/A		
51	Functionality of push buttons	N/A	N/A	Procedure passed	N/A		
52	Communication test (connection LINK-IN – LINK-OUT)	N/A	N/A	Message “E394 Communication error” occurs	N/A		
53	Date and Time	N/A	N/A	Procedure passed	N/A		
54	Restore of output power settings	N/A	N/A	Settings restored	N/A		
Inspection label							
55	Due date (month/year): _____	N/A	N/A	Adhered	N/A		

	Yes	No	Date	Signature
Unit meets test criteria:				
Name of inspection person:				
Test organization:				

CHAPTER 6: DEVICE MENU

1 SAFETY TEST 94
2 SOFTWARE VERSION 95

1 Safety Test

This function closes the output relays to perform the measurement(s) required during the inspection. Activation of this function disables the electrosurgical unit for normal operation.

1) Press the “MENU push button” to display the “Select Menu Screen” on the touch-screen.

2) Switch to the next menu page by pressing the “Next button”. Press the Button “Safety Test”.

3) Press the button “Relays On”. The button will be marked white, when the Relays are on. To perform the inspection refer to chapter 7: Inspection.

4) To exit this mode press the button “Relays Off” and press the button “Cancel” to leave the screen.

NOTE The electrosurgical unit remains in this service operation mode until the button “Relays Off” is pressed. This enables an easy measurement required by the periodic safety check even if the unit will be switched off.

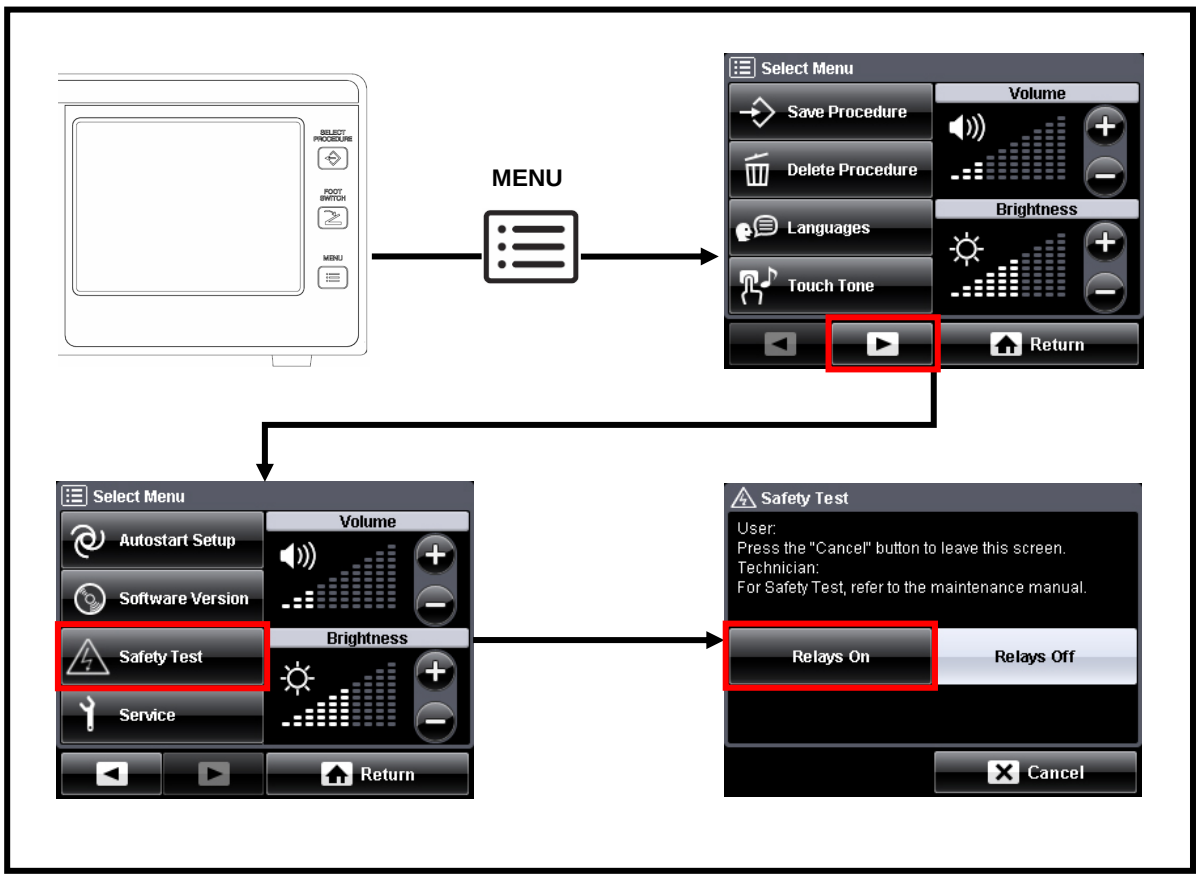


Fig. **Fehler! Verweisquelle konnte nicht gefunden werden.**.1.1. Entering the Safety Test Mode

2 Software Version

1) Press the “MENU push button” to display the “Select Menu Screen” on the touch-screen.

2) Switch to the next menu page by pressing the “Next button”. Press the Button “Software version”.

3) Read out the software version and leave the menu by pressing the button “OK”.

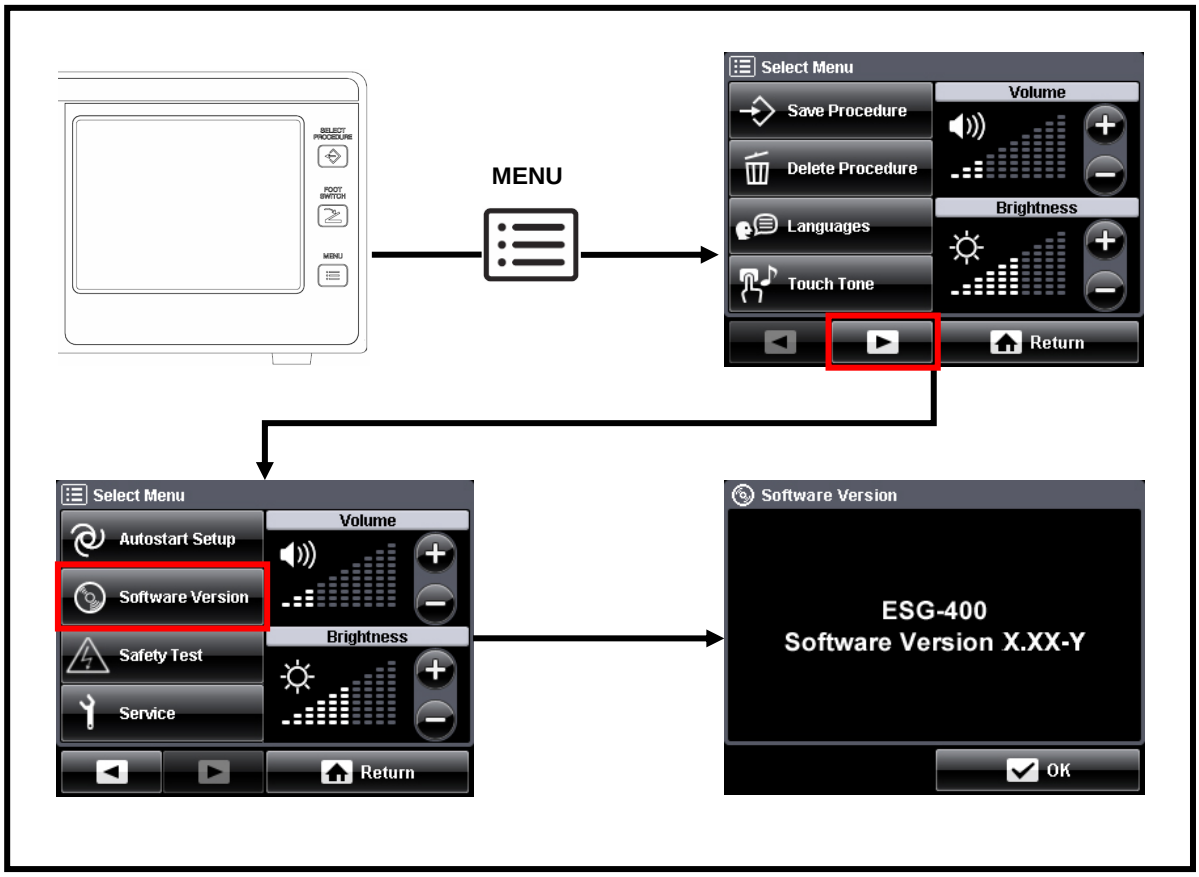


Fig. **Fehler! Verweisquelle konnte nicht gefunden werden.**.2.1. Entering the Software Version Menu

CHAPTER 7: REVISION HISTORY

3 Revision History

No.	REF No. / Revision No.	Release date	Modifications description
1	7.022.211 12/04	2012-04-27	First clearance
2	7.022.211 12/09 W-CR-11829	2012-10-12	**Chapter 5-1:** Added ESG-Textbox to the Jigs and tools list **Chapter 5-1:** Added J017 Oscilloscope to the Jigs and tools list **Chapter 5-1:** Added J018 High Voltage Probe to the Jigs and tools list **Chapter 5-2-7:** Added Steps 6 Connect high voltage probe to oscilloscope and to generator output socket (signal to right receptacle of the MONOPOLAR 1 socket and signal ground to neutral socket) **Chapter 5-2-7:** Added Steps 7 Activate the output power by pressing “CUT” at the footswitch. Record the waveform in the time range after the high power cut support pulse (ca. 100 ms after HF output start) in steady state. **Chapter 5-2-7:** Added Steps 8 Verify output waveform: The amplitude level of the output voltage must be stable. No oscillation in the frequency range of 50 … 200 Hz. A maximum amplitude fluctuation from minimum peak voltage to maximum peak voltage of 110 V is allowed for steady state. **Chapter 5-2-7:** Added Steps 9 Disconnect high voltage probe **Chapter 5-2-7:** Following step numbering updated **Chapter 5-2-7:** Added Table 7.4 good and bad examples of the output waveform **Chapter 5-2-12:** Description updated “For applicable markets” **Chapter 5-3:** Added Step 17 Amplitude fluctuation. Following step numbering updated
3	7.022.195 04/13 W-CR-13001 W-CR-12952	2013-04-04	**Chapter 5-2-1:** Fig. 5.2.2 (Japanese type plate) and Fig. 5.2.3 (Chinese type plate) added, following picture numbering updated **Chapter 3-3-1:** Part number for the double footswitch corrected ”WB50403” **Chapter 3-3-2:** Part number for the single footswitch corrected ”WB50402
4	7.022.195 09/13 W-CR-13662	2013-09-10	**Added “**On-Site-Manual” to title page **Chapter 5-2-3:** Reference at step 1 changed **Added Chapter 6:** Device Menu Following chapter numbering updated

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